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11	NORTHERN DIST	RICT OF CA	LIFORNIA		
12	SAN FRAN	CISCO DIVIS	SION		
13	IN REJUJUL LABS. INC., MARKETING.	Case No.	19-md-02913-WHO		
14	IN RE JUUL LABS, INC., MARKETING, SALES PRACTICES, AND PRODUCTS LIABILITY LITIGATION		IFFS' OMNIBUS OPPOSITION		
15	Embler Embride		ENDANTS' DAUBERT MOTIONS		
16	This Document Relates to:	Judge: Date:	Hon. William H. Orrick TBD		
17	ALL ACTIONS	Time: Ctrm.:	TBD 2		
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GLOSSARY OF KEY TERMS

Term	Definition and Citation
Altria	Altria Group, Inc., Philip Morris USA, Inc., Altria Client Services LLC, and Altria Group Distribution Company
Altria Ex.	Exhibits to the Declaration of Angela R. Vicari in Support of the Altria Defendants' <i>Daubert</i> Motion Regarding Plaintiffs' Experts
Altria Mot.	Altria Defendants' <i>Daubert</i> Motion Regarding Plaintiffs' Experts, ECF 2685-2 (unredacted version)
Boyles Dep.	ODD Ex. E, Transcript of October 28, 2021, Deposition of Steven Boyles
Boyles Rpt.	ODD Ex. D, Generic Expert Report of Steven Boyles, dated September 20, 2021
Casey Dep.	JLI Ex. 30, Transcript of November 8, 2021, Deposition of Alicia Casey
Casey Dep. (BB)	JLI Ex. 31, Transcript of November 8, 2021, BB-Specific Deposition of Alicia Casey
Casey Rpt.	JLI Ex. 1, Generic Expert Report of Alicia Casey, dated September 20, 2021
Casey Rpt. (BB)	JLI Ex. 2, BB-Specific Expert Report of Alicia Casey, dated September 22, 2021
Chandler Rpt.	JLI Ex. 3, Generic Expert Report of John Chandler, dated September 20, 2021
Chandler Dep.	JLI Ex. 32, Transcript of October 21, 2021, Deposition of John Chandler
Chandler Dep.	JLI Ex. 104, Transcript of July 12, 2021, Deposition of John Chandler
Cutler Rpt.	JLI Ex. 4, Generic Expert Report of David Cutler, dated September 20, 2021
Cutler Dep.	JLI Ex. 33, Transcript of November 3, 2021, Deposition of David Cutler
Defendants	Altria; JUUL Labs, Inc.; Adam Bowen; James Monsees; Nicholas Pritzker; Riaz Valani, and Hoyoung Huh

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Term	Definition and Citation
Drumwright Rpt.	JLI Ex. 5, Generic Expert Report of Minette Drumwright, dated September 20, 2021
Drumwright Dep.	JLI Ex. 34, Transcript of October 25, 2021, Deposition of Minette Drumwright
Eissenberg Rpt.	JLI Ex. 6, Generic Expert Report of Thomas Eissenberg, dated September 20, 2021
Eissenberg Dep.	JLI Ex. 35, Transcript of October 27, 2021, Deposition of Thomas Eissenberg
Emery Rpt.	JLI Ex. 7, Generic Expert Report of Sherry Emery, dated September 20, 2021
Emery Dep.	JLI Ex. 36, Transcript of November 4, 2021, Deposition of Sherry Emery
Emery Dep.	JLI Ex. 65, Transcript of July 30, 2021, Deposition of Sherry Emery
Grunberg Rpt.	JLI Ex. 8, Generic Expert Report of Neil Grunberg, dated September 20, 2021
Grunberg Rpt. (BB)	JLI Ex. 9, BB-Specific Expert Report of Neil Grunberg, dated September 23, 2021
Grunberg Dep.	JLI Ex. 37, Transcript of November 19, 2021, Deposition of Neil Grunberg
Grunberg Dep. (BB)	JLI Ex. 38, Transcript of December 13, 2021, Deposition of Neil Grunberg
Halpern-Felsher Rpt.	JLI Ex. 10, Generic Expert Report of Bonnie Halpern-Felsher, dated September 20, 2021
Halpern-Felsher Dep.	JLI Ex. 39, Transcript of October 19, 2021, Deposition of Bonnie Halpern-Felsher
Individual Defendants	Adam Bowen, James Monsees, Nicholas Pritzker, Riaz Valani, and Hoyoung Huh
Jackler Rpt.	JLI Ex. 11, Generic Expert Report of Robert Jackler, dated September 20, 2021
Jackler Dep.	JLI Ex. 40, Transcript of October 25, 2021, Deposition of Robert Jackler

Term	Definition and Citation
JLI Ex.	Exhibits to the Declaration of Renee Smith in Support of JUUL Labs, Inc.'s Omnibus Daubert Motions
JLI Roadmap	Introductory "Roadmap" to Defendants JUUL Labs, Inc.'s Omnibus <i>Daubert</i> Motions, ECF 2701
JLI Mot. 1	Brief #1: Defendants JUUL Labs, Inc.'s Omnibus <i>Daubert</i> Motion to Exclude Certain Marketing Opinions, ECF 2709
JLI Mot. 2	Brief #2: Defendants JUUL Labs, Inc.'s Omnibus <i>Daubert</i> Motion to Exclude Certain Addiction Opinions, ECF 2706
JLI Mot. 3	Brief #3: Defendants JUUL Labs, Inc.'s Omnibus <i>Daubert</i> Motion to Exclude Certain Opinions on Toxicity and Alleged Health Effects, ECF 2703-3 (unredacted version)
JLI Mot. 4	Brief #4: Defendants JUUL Labs, Inc.'s Omnibus <i>Daubert</i> Motion to Exclude Fact Narrations and Opinions Regarding Intent, State-of-Mind, and Legality, ECF 2708
JLI Mot. 5	Brief #5: Defendants JUUL Labs, Inc.'s Omnibus <i>Daubert</i> Motion to Exclude Opinions on Alleged Failures to Act, ECF 2707
JLI Mot. 6	Brief #7: Defendants JUUL Labs, Inc.'s Omnibus <i>Daubert</i> Motion to Exclude Opinions on Abatement, ECF 2705
Johnson Dep.	ODD Ex. I, Transcript of November 22, 2021, Deposition of Robert Johnson
Johnson Rpt.	ODD Ex. H, Generic Expert Report of Robert Johnson, dated November 5, 2021
Johnson Rpt. Addendum	ODD Ex. K, Generic Expert Report of Robert Johnson, dated September 17, 2021
Kelder Rpt.	JLI Ex. 12, Generic Expert Report of Steven Kelder, dated September 20, 2021
Kelder Dep.	JLI Ex. 41, Transcript of October 29, 2021, Deposition of Steven Kelder
Levy Rpt.	JLI Ex. 13, Generic Expert Report of Sharon Levy, dated September 20, 2021
Levy Rpt. (BB)	JLI Ex. 14, BB-Specific Expert Report of Sharon Levy, dated September 23, 2021

Term	Definition and Citation	
Levy Dep.	JLI Ex. 42, Transcript of November 9, 2021, Deposition of Sharon Levy	
Levy Dep. (BB)	JLI Ex. 43, Transcript of November 20, 2021, BB-Specific Deposition of Sharon Levy	
Lindblom Rpt.	JLI Ex. 15, Generic Expert Report of Eric Lindblom, dated September 20, 2021	
Lindblom Dep.	JLI Ex. 44, Transcript of November 8, 2021, Deposition of Eric Lindblom	
London Decl.	Declaration of Sarah London, submitted concurrently with this Opposition	
Noar Rpt.	JLI Ex. 16, Generic Expert Report of Seth Noar, dated September 20, 2021	
Noar Dep.	JLI Ex. 45, Transcript of November 5, 2021, Deposition of Seth Noar	
$\mathrm{ODDs^1}$	Nicholas Pritzker, Hoyoung Huh, and Riaz Valani	
ODD Ex.	Exhibits to the Declaration of Michael J. Guzman in Support of Non-Management Director Defendants' Omnibus <i>Daubert</i> Motions	
ODD Mot.	Notice of Motion, Motion, and Memorandum of Points and Authorities in Support of Non-Management Director Defendants' Omnibus <i>Daubert</i> Motion, ECF 2687-1 (unredacted version)	
Pltf. Ex.	Exhibits to the London Decl.	
Pratkanis Rpt.	JLI Ex. 17, Generic Expert Report of Anthony Pratkanis, dated September 20, 2021	
Pratkanis Dep.	JLI Ex. 46, Transcript of November 8, 2021, Deposition of Anthony Pratkanis	
Prochaska Rpt.	JLI Ex. 18, Generic Expert Report of Judith Prochaska, dated September 20, 2021	

¹ Although Huh, Pritzker, and Valani refer to themselves as the "Non-Management Defendants," Plaintiffs use the "Other Director Defendant" terminology utilized by the Court.

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Prochaska Rpt. (BB)	JLI Ex. 19, BB-Specific Expert Report of Judith Prochaska, dated September 23, 2021
Prochaska Dep.	JLI Ex. 47, Transcript of October 28, 2021, Deposition of Judith Prochaska
Prochaska Dep. (BB)	JLI Ex. 48, Transcript of October 29, 2021, Deposition of Judith Prochaska
Proctor Rpt.	JLI Ex. 20, Generic Expert Report of Robert Proctor, dated September 20, 2021
Proctor Dep.	JLI Ex. 49, Transcript of November 17, 2021, Deposition of Robert Proctor
Pue Rpt.	JLI Ex. 21, Generic Expert Report of Charles Pue, dated September 20, 2021
Pue Dep.	JLI Ex. 50, Transcript of October 28, 2021, Deposition of Charles Pue
Ribisl Rpt.	JLI Ex. 22, Generic Expert Report of Kurt Ribisl, dated September 20, 2021
Ribisl Dep.	JLI Ex. 51, Transcript of October 26, 2021, Deposition of Kurt Ribisl
Shihadeh Rpt.	JLI Ex. 23, Generic Expert Report of Alan Shihadeh, dated September 20, 2021
Shihadeh Dep.	JLI Ex. 52, Transcript of November 1, 2021, Deposition of Alan Shihadeh
Tackett Rpt.	JLI Ex. 24, Generic Expert Report of Randall Tackett, dated September 20, 2021
Tackett Dep.	JLI Ex. 53, Transcript of December 2, 2021, Deposition of Randall Tackett
Tackett CV	JLI Ex. 82, University of Georgia web page CV of Randall Tackett
Winickoff Rpt.	JLI Ex. 25, Generic Expert Report 1 of Jonathan Winickoff, dated September 20, 2021
Winickoff Rpt.	JLI Ex. 26, Generic Expert Report 2 of Jonathan Winickoff, dated September 20, 2021

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Term	Definition and Citation
Winickoff Rpt.	JLI Ex. 27, Generic Expert Report 3 of Jonathan Winickoff, dated September 20, 2021
Winickoff Rpt. (BB)	JLI Ex. 28, BB-Specific Expert Report of Jonathan Winickoff, dated September 23, 2021
Winickoff Dep.	JLI Ex. 54, Transcript of November 5, 2021, Deposition of Jonathan Winickoff
Winickoff Dep. (BB)	JLI Ex. 55, Transcript of November 12, 2021, BB- Specific Deposition of Jonathan Winickoff
Woolley Rpt.	JLI Ex. 29, Generic Expert Report of Sam Woolley, dated September 20, 2021
Woolley Dep.	JLI Ex. 56, Transcript of October 28, 2021, Deposition of Sam Woolley

I. INTRODUCTION

Defendants' scattershot motions span nearly every issue in the case, presenting duplicative arguments that often fail to identify specific opinions to be excluded in contravention of Rule 702 and *Daubert*. Indeed, Defendants' motions read more like closing argument, raising credibility issues and providing a roadmap to how it intends to cross-examine at trial. In the guise of methodological challenges, Defendants ask this Court to usurp the role of the jury and act as fact-finder contrary to the mandate of *Daubert* and its progeny. Of course, a "battle of the experts" does not provide an appropriate *Daubert*-related basis for excluding an expert's opinion based on sound scientific methodology. *See City of Pomona v. SQM North America Corp.*, 750 F.3d 1036, 1049 (9th Cir. 2014); *Regents of Univ. of California v. Dako N. Am., Inc.*, Case No. 05–03955 MH P, 2009 WL 1083446, at *15 (N.D.Cal. Apr. 22, 2009) (explaining that a "battle of the experts" is appropriately left to the trier of fact to resolve). For the reasons set forth below, Defendants' motions should be denied.

II. PLAINTIFFS' EXPERTS

Defendants challenge all Plaintiffs' experts' opinions at various points across their eight motions. In most instances, they only challenge unspecified portions of those opinions and fail to the specific parts of the opinions they seek to exclude. Below Plaintiffs list the experts whose opinions have been challenged and briefly state the experts' qualification and their primary opinions. The Plaintiffs' experts possess the knowledge, skill, experience, training, and education amounting to specialized expertise and they meet or exceed the liberal standards of the Ninth Circuit. They are more than qualified to testify in this matter concerning all proferred testimony. For the Court's convenience, Appendix A, included at the end of this opposition, provides a summary chart identifying citations to the sections of this opposition that discuss the listed experts.

A. Steven Boyles

Steven Boyles has been a financial forensics and business valuation expert for more than 23 years, has testified as an expert in federal and state courts, and has served as the Chair of several professional accounting organizations including the Forensic Accounting & Litigation Support Specialty Group of The International Accounting Group. ODD Ex. D, Boyles Rpt. at 2-3. He

explains how Altria's 2018 valuation of JLI was a function of the historic and projected sales of JUUL. *Id.* at 4-21. Applying Dr. Singer's damages analysis, which quantifies the portion of JUUL's sales attributable to alleged misconduct, Mr. Boyles calculates the significant portion of Altria's \$12.8B investment in JLI—and the ultimate payments received by the individual defendants—that is traceable to Defendants' wrongdoing. *Id.* at 25-41...

B. Dr. Alicia Casey

Alicia Casey, MD is a pediatric pulmonologist and clinical researcher at Boston Children's Hospital (BCH) at Harvard Medical School affiliate, with expertise in the care for children with rare interstitial and diffuse lung disease and the pulmonary effects of vaping. JLI Ex. 1, Casey Rpt. at 4. She is the Co-Founder and Co-Director of the BCH Children's Interstitial Lung Disease Program and the Director of the BCH Pulmonary Vaping Program overseeing the programs' clinical care and research initiatives. *Id.* She is also the Director of the BCH Pulmonary Fellowship Program, the largest Pediatric Pulmonary Fellowship in the country. *Id.*

In the Fall of 2019, in response to the youth vaping epidemic and the emergence of vaping-associated lung disease, she established the BCH Pulmonary Vaping Program. *Id.* at 4, 5. This multi-disciplinary Program brings together leading clinical experts in Pulmonary Medicine, Adolescent Substance Abuse, Toxicology, Pathology and Radiology to coordinate clinical, research, and advocacy efforts for patients with pulmonary symptoms related to vaping. *Id.* at 5. She has advised the Governor of Massachusetts on the health effects of vaping and serves on the Massachusetts Special Legislative Commission on Vapes, JUULs, and other e-cigarettes. *Id.* She has published 37 peer-reviewed manuscripts, including original research reports, case series, clinical practice guidelines, and clinical reviews. *Id.*

She opines on the pivotal role of JUUL in creating the vaping epidemic, the chemical components of JUUL and its inhalant toxicology concerns, the harmful pulmonary effects from JUUL, the harmful effects associated with the high nicotine content in JUUL, the toxic effect associated with flavorings and stabilizing agents in JUUL and the impact of particulate matter in JUUL on the lungs, and JUUL's lack of warnings regarding these risks. *Id.* at 7-10.

C. Dr. John Chandler

Dr. John Chandler is an expert in marketing, marketing research, marketing analytics and data science. JLI Ex. 3, Chandler Rpt. at 3, 7, 8. His academic work is centered in applied data science and his professional experience focuses on exactly the types of campaigns that JUUL planned, executed and analyzed. *Id.* at 3. Dr. Chandler is a clinical professor of marketing at the University of Montana, with a master's degree in mathematics and a doctorate degree in statistics. Id. at 3. For the past 22 years, he has worked in analytics and data science, with a focus on digital marketing. Id. He previously worked at Avenue A, the largest digital advertising agency in the world, and then for aQuantive, which provided marketing technology to large-scale advertisers and advertising agencies. Id. He has been a co-inventor and lead researcher on tools developed to assist agencies with digital advertising strategies. *Id.* at 3, 4. Dr. Chandler published the first research that identified the online phenomenon of "Cyber Monday." Id. at 3. He also spent five years at Microsoft, including a stint as Research Director at Microsoft TV. Id. at 4. In 2012, Dr. Chandler founded Data Insights, a data science consulting company. Id. Data Insights provides enterpriseclass data science to a wide range of companies, including fortune 500 companies, and has advised clients that include LinkedIn, General Mills, Thrivent Financial, eBay, Expedia, Nike, Charter Communications and The Sierra Club. Id.

Based on Dr. Chandler's study of JUUL's marketing and advertising, he offer the opinions, among others, that JUUL: seeded its marketing in events that would appeal to youth, and that would encourage youth to disseminate product information on social media; co-opted user-generated content on social media to proliferate awareness of its products in markets dominated by youth consumers; employed marketing strategies that succeeded in generating viral marketing spread that inevitably and foreseeably bled extensively into youth markets; and dominated and continues to dominate vape-related discourse on Twitter, a social media platform that skews toward youth, as a result of its marketing activities. *Id.* at 8. Dr. Chandler is uniquely qualified to offer these and the other opinions set forth in his report.

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D. Dr. David Cutler

Dr. David Cutler is one of the nation's leading public health economists who has served as a senior economic adviser for two presidential administrations, published hundreds of peer-reviewed articles, and written three books on the economics of healthcare, and has won multiple awards for his work in health economics. JLI Ex., 4, Cutler Rpt. ¶2, 4, 5. He is currently the Otto Eckstein Professor of Applied Economics at Harvard University, and also holds appointments at the Kennedy School of Government and the School of Public Health. *Id.* at ¶1. He is a former editor or associate editor to several peer-reviewed publications, including the Journal of Health Economics, the Journal of Economic Perspectives, the Journal of Public Economics, and the World Health Organization Bulletin. *Id.* at ¶2. He also currently serves as President of ASHEcon, the leading professional organization for health economists. *Id.* ¶2. Of particular relevance to this litigation, Dr. Cutler has published extensively on the economic and public health impacts of tobacco, and regularly analyzes the relationship between addictive goods and societal harms, including as an expert witness. *Id.* at ¶2, 5.

Dr. Cutler offers opinions that JUUL and Altria were responsible for the recent increase in youth usage of e-cigarettes. *Id.* at ¶¶ 139–172 (role of JUUL); and ¶¶177-208 (role of Altria). These opinions were based on standard economic and econometric methodologies, including utilization of direct and indirect regressions that relied on numerous variables and data to establish these relationships. *Id.* Dr. Cutler also concludes from an economic perspective that there is a youth vaping epidemic, that there is no evidence that youth use of e-cigarettes substituted for combustible cigarette use as JUUL contends, and there are both short and long-term costs and harms associated with youth use of e-cigarettes. *Id.* at ¶.

E. <u>Dr. Minette (Mimi) Drumwright</u>

Dr. Drumwright has dedicated her decades-long career to the teaching and practice of marketing, advertising, ethics in advertising and corporate conduct—first as an industry insider at a public relations firm and then as a professor and researcher at the University of Texas and Harvard University. JLI Ex. 5, Drumwright Rpt. at 1-3. Dr. Drumwright is the William David Blunk Memorial Professor and a University Distinguished Teaching Professor at the University of Texas

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at Austin (UT Austin). *Id.* at 1. She has a joint appointment in the Stan Richards School of Advertising & Public Relations in the Moody College of Communication and in the Business, Government & Society Department of the McCombs School of Business. *Id.* She serves as director of the Communication and Leadership Degree, a degree that she was instrumental in creating. *Id.* Dr. Drumwright has conducted extensive research not just on the topics above but also behavioral ethics, public relations, and strategic marketing communications. *Id.* at 4. As part of her research, Dr. Drumwright has received numerous grants to pursue her work; she has published articles in peer-reviewed journals and received numerous accolades from marketing organizations; and she has been invited to present her research at international institutions of higher learning. *Id.* at 2, 4, 6. Just as important, Dr. Drumwright has sought to guide the profession with expertise by serving on the board of the numerous peer-reviewed journals in the area of marketing and advertising. *Id.* at 3.

Dr. Drumwright is uniquely qualified to offer opinions as to the nature and impact of JUUL's marketing scheme that attracted youth to JUUL, a highly addictive nicotine-containing product. Her extensive research, study and publication in the fields of marketing, advertising, ethics, and corporate social responsibility qualifies her to offer opinions on the nature of JUUL marketing and advertising and the corporate codes and standards applicable to the JLI Board of Directors, and to Altria, in their marketing and advertising decisions.

F. Dr. Thomas Eissenberg

Dr. Thomas Eissenberg is both a Professor of Psychology and the Co-Director of the Center for the Study of Tobacco Products at Virginia Commonwealth University. *Id.* at 4. Since 1997, almost all of his focus has been on tobacco and nicotine, and Dr. Eissenberg has been instrumental in researching—and developing methodologies for researching—novel tobacco products. *Id.* at 4-5. Since the commercial introduction of ENDS to the US, Dr. Eissenberg has been on the forefront of researching and developing methodologies to research, the effects of ENDS products in humans, including their nicotine delivery profile, subjective effect profile, influence on user behavior, and ability to substitute for traditional tobacco products (e.g., combustible cigarettes, smokeless tobacco). *Id.* at 5-6. Based on his expertise in the evaluation of novel tobacco products, he was

appointed as a standing member of the FDA's Tobacco Product Scientific Advisory Committee (TPSAC) from 2011-2017. *Id.* He was also a Contributing Editor to the 2016 U.S. Surgeon General's report entitled "*E-Cigarette Use Among Youth and Young Adults: A Report of the Surgeon General*": I led the drafting of Chapter 3 entitled "Health Effects of E- Cigarette Use Among U.S. Youth and Young Adults." *Id.* at 8, 9.

Dr. Eissenberg's qualifications provide him with the expertise to assess JUUL's design defects and the inadequacy of JUUL's warnings. His assessment included extensive analysis of JUUL's abuse liability, including its pharmacokinetic (PK) profile. JLI Ex. 6, Eissenberg Rpt. at 37, 66-68, 74-80. Based on independent studies, and JLI's own studies, Dr. Eissenberg reached two core opinions: (1) JUUL's abuse liability is unreasonably high due to JUUL's high nicotine concentration, additives that promote the delivery of large doses of nicotine, flavors that appeal to non-smokers, and design features that promote concealed use; and (2) the JUUL's design process was and is inadequate, but raised warning signs of the JUUL's addiction risks that JLI ignored before bringing the product to market in 2015. *Id.* at 38-68; 98-115. Dr. Eissenberg's opinions are based on his unrivaled expertise as a public health researcher specializing in novel tobacco products and, specifically, electronic eigarettes. *Id.* at 4, 7, 8.

G. Dr. Sherry Emery

Dr. Sherry Emery is a Senior Fellow in the Public Health Group and Director of the Social Data Collaboratory at NORC at the University of Chicago. JLI Ex. 7, Emery Rpt. at 2. She has spent close to 25 years researching the effects of tobacco control communication and policy, as well as the effects of tobacco advertising and marketing. *Id*.

Currently, Dr. Emery is overseeing research for the CDC regarding the effects of social media marketing and tobacco pricing on e-cigarette sales. *Id.* at 3. She is also the Principal Investigator on an NIH grant involving research on the effects of influencer marketing on youth use of flavored tobacco products, as well as the Principal Investigator on a Robert Wood Johnson Foundation grant investigating the effects of bans on flavored tobacco products. *Id.* Dr. Emery, who has published more than 100 peer-reviewed articles and given hundreds of presentations on e-cigarette marketing and tobacco use in youth, recently published an article in Tobacco Control titled

"Characterizing JUUL-Related Posts on Instagram." Dr. Emery is also a reviewer for multiple peerreviewed journals, including Tobacco Control and Nicotine & Tobacco Research. *Id.* at 4.

Dr. Emery is well-qualified to assess JUUL's unique appeal to youth and its popularity among youth, as driven by the Defendants' promotion of the product. JLI Ex. 7, Emery Rpt. at 7-8. She opines that Defendants' use of viral marketing and advertising techniques unreasonably attracted youth to JUUL, and their use of social media in particular exploited youth susceptibility to advertising and marketing. *Id.* Dr. Emery further opines that Defendants' viral marketing caused or substantially contributed to the epidemic of youth e-cigarette use in the United States. *Id.* .

H. Dr. Neil Grunberg

Dr. Grunberg is an addiction and psychology expert who is highly qualified to offer opinions on the addictiveness of JUUL, the reinforcing effects of Defendants' marketing scheme, and whether JUUL carries a particularly high abuse liability for youth. Dr. Grunberg is a leading authority on nicotine, addiction, and the pharmacology and psychology of addiction. JLI Ex. 8, Grunberg Rpt. at ¶4-5. He has researched, taught, and published on nicotine addiction for over forty years, including a particular focus on the biobehavioral and psychopharmacologic effects of nicotine that entails evaluating how an individual becomes addicted to nicotine, what makes nicotine products more or less addictive, and the effects on the brain due to nicotine exposure. *Id.*; see also id. at ¶ 8-11. He has also served as a lead scientific editor of the 1988 United States Surgeon General's Report (on Nicotine Addiction) and of the 1990 Report (on the Health Benefits of Smoking Cessation), and for the 1998 Robert Wood Johnson Foundation's Youth Tobacco Prevention Initiative Report. *Id.* at ¶ 2. Dr. Grunberg has trained thousands of medical students to become physicians and clinical psychologists, and regularly advises practitioners on assessing addiction in patients, including the effects from such addiction. *Id.* at ¶ 7, 12, 14-16.

Defendants' critique of Dr. Grunberg is primarily limited to taking issue with his qualifications to give opinions about the addictiveness of JUUL based on Dr. Grunberg not conducting his own study to assess the potential for addiction from JUUL. Yet, Dr. Grunberg's expertise is in nicotine and in the psychology of addiction make him uniquely qualified to assess any nicotine product for its abuse liability and attractiveness to youth. It is for this reason that Dr.

Grunberg was appointed to co-author two critical Surgeon General Reports, in which Dr. Grunberg details not only how one becomes addicted to nicotine, but also identifying the factors that influence addiction. *Id.* at ¶¶ 11. Dr. Grunberg's four decades of expertise qualify him to examine JUUL, which is a nicotine-containing tobacco product, and assess its potential for abuse. His expertise in psychology and the psychology of addiction in particular, likewise qualifies him to opine on how JUUL's marketing practices impact an individual's perception of JUUL, and how those perceptions impact initiation, and later addiction to JUUL products.

I. <u>Dr. Bonnie Halpern-Felsher</u>

Dr. Halpern-Felsher is a professor of Pediatrics in the Division of Adolescent Medicine, Department of Pediatrics, at Stanford University's School of Medicine. JLI Ex. 10., Halpern-Felsher Rpt. at 2. Having a background in developmental psychology, she has conducted research on the numerous facets involved in the health-related decision-making and assessment of risks by adolescents and young adults. *Id* at 2-3. Importantly, Dr. Halpern-Felsher has researched the factors that influence adolescent and youth engagement in risky behaviors, such as nicotine use. *Id*.

The results of her research were used to create a nationally recognized tobacco prevention program, called the Tobacco Prevention Toolkit. *Id.* at 3. Dr. Halpern-Felsher's Toolkit contains an evidence-based curriculum and is currently used as an educational tool in schools across the country. *Id.* Dr. Halpern-Felsher has served on six committees for the National Academies of Sciences, Engineering, and Medicine that focused on the health of adolescents and young adults, including prevention and reduction of tobacco use. *Id* at 4. Her research has been the subject of more than 170 publications and more than 300 presentations, including presentations to the CDC, FDA, NIH, and Congress. *Id.*

Dr. Halpern-Felsher's exceptional qualifications provide support for her opinions that Defendants failed to act responsibly to protect adolescents and young adults from using JUUL. See JLI Ex. 10, Halpern-Felsher Report at 8-12. Dr. Halpern-Felsher opines that Defendants acted unreasonably in branding, marketing, advertising, and selling JUUL in a way that was unnecessarily attractive to adolescents and young adults. *Id.* She further opines that Defendants were aware of the potential for adolescents and young adults to be attracted to the product, and they failed to

adequately inform adolescents and young adults about the dangers and unique risks JUUL posed to them. *Id.* She opines Defendants' youth prevention measures were also inadequate, and Defendants' conduct caused or substantially contributed to the youth vaping epidemic and increased nicotine use in adolescents and young adults. *Id.*

J. Dr. Robert K. Jackler

Dr. Jackler is a surgeon, professor, and former Chair of Otolaryngology-Head and Neck Surgery at Stanford University's School of Medicine. JLI Ex. 11, Jackler Rpt. at 9. Dr. Jackler is the founder of the Stanford Tobacco Research Collaborative and the research group Stanford Research into the Impact of Tobacco Advertising (SRITA), and he has studied tobacco industry marketing for more than 15 years. *Id.* SRITA has created the largest repository of tobacco advertising imagery in the world. *Id.*

Dr. Jackler has also authored numerous peer-reviewed studies and academic papers on JUUL, as well as the tobacco industry. *Id.* at 11; *see also* Pltf. Ex. 47, Jackler CV at 36. Dr. Jackler is co-author on peer-reviewed articles related to JUUL that have been published in *Tobacco Control*, including its high nicotine content and stealth features. *Id.* One of Dr. Jackler's most well-recognized and often cited article is "Nicotine Arms Race", published in 2019 in *Tobacco Control*. *Id.* He has also published academic articles on JUUL's marketing, including an analysis of its campaigns during JUUL's first three years on the market, as well as JUUL's history of advertising on social media. *Id.* Dr. Jackler's extensive study of the tobacco industry has also resulted in the publication of numerous peer-reviewed articles in journals such as, *Tobacco Control and JAMA*, *on* a variety of topics related to his testimony in this case, such as addiction, flavored tobacco products, smoking related cancers, among others. Id.

Based on more than a decade of study and analysis of the effects of tobacco advertising, Dr. Jackler opines that the Defendants' branding, marketing, and advertising were unreasonably attractive to youth, were misleading and deceptive, and did not adequately warn about the risks associated with use of the product. *Id.* at 18-24. Dr. Jackler concluded Defendants knew or should have known their marketing, branding, and advertising had an unreasonable likelihood of attracting

youth, yet they failed to take appropriate action, and their conduct substantially contributed to the youth vaping epidemic. *Id.*.

K. Robert W. Johnson

Robert W. Johnson is an expert with more than 40 years experience in financial and economic analysis, who has evaluated the financial condition of Defendants for purposes of satisfying any potential punitive damage award made by the jury. ODD Ex. H, Johnson CV. Johnson is well-qualified to render opinions at trial regarding Defendants' ability to pay punitive damages. He has an MBA from Stanford University and an undergraduate degree from Baruch College with a major in economics. *Id.* Over the course of several decades, numerous state and federal courts have found him to be a qualified economic expert permitted to testify on economic issues, including punitive damages in a wide range of cases, including cases involving tobacco products. *Id.* at 1-2.

Only Defendants Huh, Pritzker and Valani seek to exclude Mr. Johnson's testimony relating to the measure of their financial condition for purposes of a punitive damages award. These Defendants criticize Mr. Johnson's methodology based on their assertion that their special dividend profits received from JLI are irrelevant to Mr. Johnson's financial analysis and opinions. Based on his exceptional qualifications, Mr. Johnson explains the appropriateness of considering the Defendants' receipt of substantial dividends from JLI in the context of illustrating the basis for his conclusions as to their financial condition as it relates to their ability to pay punitive damages. ODD Ex. K, Johnson Rpt. at 4.

21 L. <u>Dr. Sharon Levy</u>

Sharon Levy, M.D. is a pediatrician board certified in Developmental Behavioral Pediatrics and Addiction Medicine, and an Associate Professor of Pediatrics at Harvard Medical School. JLI Ex. 13, Levy Rpt. at 5. She received her undergraduate degree from the University of Pennsylvania, her medical degree from New York University, and received a Master of Public Health from Harvard University. *Id.* She directs the Adolescent Substance Use and Addiction Program at Boston Children's Hospital, which is comprised of clinical care, research and training components. *Id.* She supervises a clinical substance use disorders program for children and teens at Boston Children's

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Hospital that conducts more than 4000 visits per year, and she has more than 20 years of experience evaluating and treating adolescents with substance use problems and disorders. Id. Dr. Levy has conducted research funded by the National Institutes of Health and private foundations that has led to the development of screening tools and brief intervention strategies to address adolescent substance use in pediatric primary care. *Id.* She receives support from the Substance Use and Mental Health Services Administration to capacitate substance use treatment in pediatric primary care by integrating trained adolescent substance use counselors while also supporting the skills and knowledge primary care providers. *Id.* Dr. Levy also directs the nation's first ACGME accredited fellowship training program in Pediatric Addiction Medicine and serves on the boards of directors of the American College of Academic Addiction Medicine and the Association for Multidisciplinary Research and Education in Substance use and Addiction. *Id.* She has more than 80 published articles in the medical literature with the vast majority relating to substance use issues, including epidemiology on adolescent substance use. Id. at 5, 6.

Dr. Levy is well qualified to opine as to general issues regarding the addictive properties of JUUL and its impact on youth, which she has observed in her clinical care as well as its impact on B.B. who she has met with and interviewed. JLI Ex. 14, Levy Rpt. (B.B.) at 8, 38-44. Having reviewed internal JLI documents she opines that JLI knew that its high dose nicotine was not necessary to deliver satisfaction to smokers and encourage switching from combustible cigarettes. She describes several features that made JUUL particularly and uniquely attractive to youth and that the introduction of JUUL to the e-cigarette market caused the youth vaping epidemic. Id. at 29-31. She explains how nicotine addiction in youth is difficult to treat. *Id.* at 45-46.

Μ. **Eric Lindblom**

Mr. Lindblom has expertise in analyzing the complex regulatory and public health scheme regarding tobacco products, including the overlapping elements that are protective of youth, adult consumers, and public health, which render him highly qualified to address similar issues in this case. He is a Senior Scholar at Georgetown Law's O'Neill Institute for National & Global Health Law, where he previously served as the Director for Tobacco Control and Food & Drug Law. JLI Ex. 15, Lindblom Rpt. at 2. He served as the Director of the Office of Policy at FDA's Center for

Tobacco Products at the U.S. Food and Drug Administration and was General Counsel and Director for Policy Research at the Campaign for Tobacco-Free Kids, where he had worked on tobacco control legal and policy issues beginning in 1998. *Id.* In addition to his extensive work experience in the regulatory field, Mr. Lindblom has authored numerous studies relating to a broad range of tobacco control issues, including those pertaining to e-cigarettes. *Id.* at 3-5. Mr. Lindblom's academic training and experience provided the basis for his expertise on topics involving the historical and evolving framework of federal, state, and local laws and regulations related to tobacco products, including e-cigarettes, and their design, marketing, sale, and use. *Id.* at 6.

Mr. Lindblom explains the complex regulatory framework that existed when JUUL designed, developed, marketed, and sold its e-cigarettes, including tobacco control laws and regulations, common law standards for manufacturers, tobacco control court rulings and settlement agreements, and research-based tobacco control findings and expert recommendations, all of which clearly established the standards for e-cigarette manufacturers like JUUL. *Id.* at 10-97. Mr. Lindblom concludes that JUUL failed to meet these standards and, in so doing, failed to act as a reasonable and responsible manufacturer of e-cigarettes in the context of that regulatory framework. *Id.* at 98-102.

N. Dr. Seth Noar

Dr. Noar is an expert in health communications with a PhD in Social Experimental psychology from the University of Rhode Island. JLI Ex. 16, Noar Rpt. at 1, 2. Dr. Noar is recognized as the James Howard and Hallie McLean Parker Distinguished Professor in the Hussman School of Journalism and Media at the University of North Carolina (UNC), a leading nationally accredited professional journalism and communication school. He has taught at UNC since 2011 and currently teaches a graduate course on health communication which examines how messaging and communication campaigns can be used to improve behaviors. *Id.* at 2. Dr. Noar has extensively studied, researched, and published in the field of health communications, including tobacco prevention and control, with recently focusing on studying communication with youth about the risks of e-cigarettes. *Id.* at 3, 4. He has spent several years studying the effects of cigarette pack warnings and led the first meta-analysis of experimental studies of pictorial warnings and

synthesizing the effects of 37 studies consisting of 33,613 participants. *Id.* at 3. He has led and collaborated on surveys, experiments, and focus groups of thousands of youth, young adults, and adults. Dr. Noar also regularly interacts with youth through a Youth Advisory Board created through a grant-funded project, which he uses as a platform for receiving feedback on message concepts and messages designed to prevent vaping among youth. Dr. Noar has led studies examining the use of text-messaging to communicate with adolescents about e-cigarette risks and has studied the perceived effectiveness of vaping prevention ads on adolescents and young adults, as well as their responses to product warnings about e-cigarettes that focus on health harms associated with product use. *Id.*

Dr. Nor gives opinions in this case regarding the processes used by JUUL to communicate to youth about product risks, including the best practices for health warnings. *Id.* at 1. He is well equipped to offer opinion on the inadequacy of JUUL's warnings and on what JUUL should have done to adequately warn youth about the nicotine addiction and other health risks of using its products. *Id.* at 6. Among other things, Dr. Noar explains how JUUL failed to follow best practices for warnings, as well as the consequence of such failures that led dangerous misperceptions by youth about JUUL's health risks. *Id.*

O. Dr. Anthony Pratkanis

Dr. Pratkanis is qualified to offer opinions concerning the nature and impact of JUUL's marketing scheme that attracted youth to JUUL, how JUUL's marketing was a substantial cause of the epidemic of e-cigarette use among youth, and actions by Altria that contributed to that epidemic. Dr. Pratkanis is an experimental social psychologist and Emeritus Professor of Psychology at the University of California-Santa Cruz. JLI Ex. 17, Pratkanis Rpt. at 1. As a professor, he has taught courses on social influence, social psychology, research methods, consumer psychology, and the nature of belief. *Id.* Previously, he taught classes in marketing management, buyer behavior, and advertising at Carnegie-Mellon University. *Id.* Dr. Pratkanis's primary area of research is social influence and belief formation, including mass communications, deceptive advertising, sales practices, and economic fraud. He has written dozens of scholarly articles, and he has written a

book about social influence in the mass media, including deceptive advertising. *Id.* Dr. Pratkanis had formal post-doctorate training in marketing at Carnegie Mellon. *Id.* at Appendix A.

Dr. Pratkanis's opinions address JUUL's unique selling proposition (USP), which is the core characteristic of the brand—i.e., the message to consumers about the unique benefit provided by the brand. Dr. Pratkanis determined JUUL's USP to be "[a] tech lifestyle product that satisfies." *Id.* at 47. The broader USP message is that JUUL is a technological breakthrough that radically changes the nature of smoking with a more satisfying nicotine experience and one that is unlike past nicotine offerings in terms of health, safety, and risks. *Id.* at 5, 6. Dr. Pratkanis's conclusions find direct support in JLI's own documents.

Dr. Pratkanis also analyzed and described in great detail how JUUL caused an epidemic of youth nicotine addiction. In doing so, Dr. Pratkanis employed scientific principles and multiple models that evaluate causation which have been recognized in the peer-reviewed literature, including epidemiological criteria that also have featured in reports and conclusions by the U.S. Surgeon General. *Id.* at 60-108. Dr. Pratkanis also considered and ruled out potential alternative causes for the youth e-cigarette epidemic, and he carefully analyzed the role of JUUL's marketing, its Board of Directors, and Altria in causing and contributing to the youth epidemic. *Id.* at 23-55.

P. Dr. Judith Prochaska

Dr. Judith Prochaska is a clinical psychologist with a Master's Degree of Public Health, who offers opinions primarily related to the effects to youth from nicotine exposure and JLI's contribution to the youth vaping epidemic. JLI Ex. 18, Prochaska Rpt. at 1, 4. She also offers opinions related to Altria's investment in JLI and their contribution to youth use of JUUL. *Id.* at 5. Her opinions are based on well-rounded and esteem qualifications. She is a tenured professor of Medicine with the Stanford Prevention Research Center where she treats patients suffering from nicotine addiction, including JUUL addicts. *Id.* at 1, 16. Dr. Prochaska has addiction medicine privileges at Lucile Packard Children's Hospital, where she also directs Stanford Cancer Center's Tobacco Treatment Service. *Id.* at 1. Dr. Prochaska also is a faculty member of the Stanford Research into the Impact of Tobacco Advertising (SRITA) collaborative, an online library of 50,000+ tobacco and e-cigarette advertisements. *Id.*

Dr. Prochaska has led multiple research grants as a Principal Investigator, focusing on topics such as, tobacco use, including e-cigarettes, and treatments for nicotine addiction. *Id.* Among others, she has received grants from the National Institutes of Health, the American Cancer Society, and the State of California Tobacco-Related Disease Research Program. *Id.* Dr. Prochaska has authored or coauthored over 250 peer-reviewed publications in smoking cessation, nicotine dependence, e-cigarettes, smoking and disease, tobacco marketing, among others relevant to her opinions in this case. *Id.* at 2. Notably, Dr. Prochaska is a contributing author on the 2020 Surgeon General's Report on *Smoking Cessation*. *Id.* Her credentials earned her the position of past-President of the Society for Research on Nicotine and Tobacco (SRNT), the international scientific society aimed at stimulating new knowledge concerning nicotine and tobacco. *Id.* at 1, 2. She has also been consulted by many federal and public health organizations on tobacco and nicotine topics, including the World Health Organization's (WHO). *Id.* at 2. Dr. Prochaska's training and professional experience provides her with a unique expertise to discuss the very topics Defendants challenge here. In fact, she was approached to serve as a consultant to JUUL Labs Inc. (JLI) as a scientist and as an expert witness in litigation. *Id.*

Dr. Prochaska opines that nicotine exposure during youth is more likely to result in addiction and that youth and young adults are at a higher risk of long-term, long-lasting effects of exposing their developing brains to nicotine. *Id*. at 4. She concludes that JUUL's addiction liability is at least as great as that of a cigarette, and likely greater for youth, due partially to JUUL's patented nicotine salt formulation, attractive flavors and stealth design features and that JUUL failed to meet a reasonable consumer expectation of delivering nicotine at consistent levels under normal conditions and can exceed that of a cigarette in terms of speed of delivery of nicotine. *Id*. at 4, 5. Dr. Prochaska also offers opinion regarding JUUL's faulty design and the impact on end users. *Id*. She further offers opinions addressing JUUL's failure to limit/restrict the sale of its products to youth. *Id*. at 5. Finally, she concludes that JLI recklessly marketed its products as modified risk without proper evidence to make such claims. *Id*. As it relates to Altria, Dr. Prochaska opines regarding Altria's liability stemming from their investment in JLI, despite knowledge of JUUL's

youth use problem and providing manufacturing, distribution, and promotional services that expanded JUUL's footprint and sales. *Id.* at 5, 6.

Q. <u>Dr. Robert Proctor</u>

Dr. Robert Proctor has a Masters of Science and PhD in the History of Science from Harvard University. He is currently a Professor of the History of Science at Stanford University, as well as a Professor, by courtesy, of Pulmonary and Critical Care Medicine. JLI Ex. 20, Proctor Rpt. at 2. He has published extensively on the history of cancer, tobacco, and adverse health effects caused by cigarettes, as well as the history of the growth of knowledge of tobacco-cancer links, including numerous books. *Id.* He has been qualified as an expert witness and testified on behalf of plaintiffs at trial in over 200 cases against the U.S. tobacco industry. *Id.* He has received a multitude of honors and awards for his scholarly work. *Id.*

Drawing on his extensive background with the history of nicotine and the tobacco industry, Dr. Proctor offers opinions on the deceptions created by JUUL and Altria through the advertising of JUUL, regarding the harms related to JUUL use. *Id.* at 4. He concludes that JUUL and Altria created the confusion created by JUUL's marketing of flavors by suggesting that inhaling nicotine is no different than ingesting caffeine, thereby creating confusion to consumers of the health impacts between inhalation and ingestion of nicotine. *Id.* Dr. Proctor also offers opinions about the inadequacy of testing JUUL prior to releasing it on the market, as well as the impact on youth from JUUL's aggressive marketing campaigns that included a sharp rise in teen vaping. *Id.* Finally, Dr. Proctor analyzed JUUL's marketing tactics by comparing them with Big Tobacco and concluded that JUUL used many of the same deceptive techniques. *Id.* at 5.

R. <u>Dr. Charles Pue</u>

Dr. Pue is a pulmonologist qualified to opine that JUUL aerosol and vapor can cause or contribute to lung disease. He is an attending physician in the Pulmonary and Critical Care Division of Sarasota Memorial Hospital, a Clinical Assistant Professor of Medicine at Florida State University, and the clinical instructor at two schools of medicine, Florida State University and Lake Erie College of Medicine. JLI Ex. 21, Pue Rpt. at 1. He is also the Clinical Trials Investigator for the Clinical Research Center at Sarasota Memorial Hospital. *Id.* at 1. Dr. Pue has extensive

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experience treating patients with lung injuries who were exposed to one of the more toxic chemicals in the Juul aerosol, diacetyl, and in 2017 he reported one of the earliest identified cases of acute lung injury caused by vaping. *Id.* at 2.

S. Dr. Kurt Ribisl

Dr. Ribisl is a tobacco regulatory science expert with a focus on sales and marketing of tobacco products at retail and online vendors. Dr. Ribisl has over 25 years of experience in tobacco control policy research and has authored over 160 scientific articles in the field, leading to him being recognized as a Highly Cited Researcher in 2019 and 2020 by Clarivate – an acclaimed list that highlights researchers and social scientists who produced multiple highly cited papers ranking in the top 1% by citations for their field and year of publication. JLI Ex. 22, Ribisl Rpt. at 2. Dr. Ribisl also received the Joseph W. Cullen Award for Excellence in Tobacco Research from the American Society of Preventive Oncology (2016). Id. During his distinguished career, Dr. Ribisl has affiliated with many federal agencies, serving as the principal investigator on tobacco control research grants from the National Institutes of Health and Centers for Disease Control, among other federal agencies. Id. He was a voting member of the Tobacco Products Scientific Advisory Committee for the US Food and Drug Administration Center for Tobacco Products. *Id.* Notably, Dr. Ribisl is a contributing author to three US Surgeon's General reports on tobacco use including: Preventing Tobacco Use Among Youth and Young Adults (2012), E-cigarette Use Among Youth and Young Adults (2016), and a report that is currently being developed. *Id.* The results of one of Dr. Ribisl's studies was instrumental in passing the 2009 Prevent All Cigarette Trafficking Act. *Id.* at 2-3, which strengthened the age verification requirements for online purchases of cigarettes. Id. Lastly, he coauthored a study in JAMA Pediatrics, the first examining whether Internet vendors sell e-cigarettes to minors, which was instrumental in the FDA passing regulations making it illegal for Internet vendors to sell e-cigarettes to minors. *Id.* at 3. Dr. Ribisl now serves as the Chair of the Department of Health Behavior at the University of North Carolina, Gillings School of Global Public Health. *Id.* at 2.

Dr. Ribisil is qualified to opine about JUUL's youth prevention practices related to age and identify verification of purchasers at retail stores and online, JUUL's marketing of their devices

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and pod refills at retail outlets, and the Altria-JUUL partnership and its impact on the sales and marketing of JUUL products.

T. Dr. Alan Shihadeh

Dr. Shihadeh is an MIT-trained mechanical engineer who has long studied ENDS products, including toxicant emissions, human puffing behaviors, aerosol generation and sampling, and related nicotine pharmacokinetics. JLI Ex. 23, Shihadeh Rpt. at 2-4. JLI's Vice President of R&D Chemistry, Dr. Dan Myers, acknowledged in deposition that Dr. Shihadeh is a "leading researcher" and an authority in the ENDS space. Pltf. Ex. 11, D. Myers at 537:20-538:9. He is a Clarivate Highly Cited Researcher, one of approximately 6400 researchers world-wide who are recognized for authoring numerous influential papers whose citations are in the top 1% of their fields. *Id.* at 3. Much of his research into novel tobacco products, including ENDS, has been funded with support from the NIH and FDA. Id. Dr. Shihadeh regularly serves as a scientific expert to the World Health Organization's Study Group on Tobacco Product Regulation. Id. As an expert on device engineering and design, human puffing behaviors, and aerosol analysis., he has extensively published on how design choices can impact aerosol—and nicotine—emissions. *Id.* at 2-4. He also has studied and opines upon the pharmacological relationship between nicotine emissions of tobacco products and blood-level exposure in users. Id.

Relying on JLI's internal studies, independent research, and his own peer-reviewed, published research on JUUL, Dr. Shihadeh opines on how and why JUUL's design informs consumer use patterns that reflect its high abuse liability. JLI Ex. 23, Shihadeh Report at 2-57. Dr. Shihadeh characterizes JUUL's performance—including the physical and sensory aspects and pharmacokinetic consequences of JUUL's seemingly mild but extraordinarily potent nicotine delivery. *Id.* Given Dr. Shihadeh's breadth of education and experience, he is uniquely qualified to address how JLI's design choices led to widespread adoption among youth and non-smokers.

Dr. Randall Tackett U.

Dr. Tackett is a toxicologist and pharmacologist qualified to opine about the chemicals known to be in Juul's aerosol, their toxicological profiles, and health risks to users of the Juul products. JLI Ex. 24, Tackett Rpt. at 4, 5. As a tenured professor of Toxicology and Pharmacology

at the University of Georgia, he teaches undergraduate and post-graduate medical students toxicology, pharmacology, pharmaceutical and biomedical sciences, regulatory affairs, ethics, and other areas. *Id.* at ¶2. Dr. Tackett has published 82 scientific articles in toxicology, including the adverse effects of chemicals in animals and humans. *Id.* He has served as a peer-reviewer for six academic journals and has been a grant reviewer for the National Institute of Health, the Centers for Disease Control and Prevention, the American Heart Association, and other well-regarded organizations. *Id.* Dr. Tackett's distinguished credentials have earned him the role of both presenting to and training FDA employees regarding pharmacology, pharmacokinetics, and drug design and development. *Id.* at ¶4.

Defendants do not allege that Dr. Tackett is unqualified to proffer the opinions he has given. Defendants only critique Dr. Tackett's methodology, which they have broadly mischaracterized. Dr. Tackett, relied on over 30 epidemiological studies, meta-analyses, and systemic reviews in addition to his robust toxicity and chemical analyses. *Id.* at 50-54. Dr. Tackett also examined individual chemicals in the JUUL products, conducted his own dose analysis of the most toxic compound, relied on the published literature dose analyses, examined laboratory and cellular experiments, and analyzed the animal studies. *Id.* at 5. Based on the methodology used by Dr. Tackett in this case, his opinions match the primary published systemic review, which concludes "...the evidence supports the conclusion of a real relationship between e-cigarettes and respiratory disorders," *id.* at 54, and also match JUUL'S non-litigation-oriented opinion in the PMTA that "[i]nhaling nicotine containing ENDS aerosol is likely to have consequences for respiratory health... *Id.* at 5 ("[A]dolescents who tried ENDS reported more respiratory symptoms than those who did not." *Id.*

V. Dr. Jonathan Winickoff

Dr. Winickoff is a pediatrician and an expert in youth tobacco control and public health who is undisputedly qualified to offer opinions on various subject matters relevant to this case. JLI Ex. 25, Winickoff Rpt. at 2. He is a practicing pediatrician at Massachusetts General Hospital and Professor of Pediatrics at Harvard Medical School with training and experience in health services research, medical ethics, neurobiology, statistics, and behavioral theory. *Id.* Dr. Winickoff is the

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current Director of Pediatric Research at the Massachusetts General Hospital (MGH) Tobacco Research and Treatment Center where he collaborates with the many researchers at MGH and in the broader Harvard system who study tobacco control. *Id.* at 3. He has received numerous awards, including the HHS Secretary's Award for Distinguished Service for "protecting the health of the United States public," and the Academic Pediatric Association Health Policy Award for cumulative public policy and advocacy efforts that have improved the health and well-being of infants, children, and adolescents. Id. at 2. He served for 7 years as the Chair of the American Academy of Pediatrics (AAP) Julius Richmond Center of Excellence Tobacco Consortium, leading a national group of researchers to address tobacco control issues that affect children, adolescents, young adults, parents, and other family members. Id. He currently serves as Director of Translational Research for the AAP Richmond Center, where on behalf of over 50,000 AAP member pediatricians in the United States, he translates tobacco control research into clinical practice, public policy, and real-world community strategies using tobacco control initiatives to improve the public health of the nation's youth. *Id.* He has authored or co-authored over 150 peer-reviewed publications, and he was selected by the AAP to represent the Academy in testimony before Congress at hearings examining JUUL's role in the youth nicotine epidemic. *Id.* at 3.

Dr. Winickoff's opinions will aid the jury in understanding numerous issues highly relevant to this case, including among others the basic science of tobacco and nicotine; the physiologic vulnerability of youth to nicotine and nicotine addiction; the impact of youth nicotine use on mental health and progression to other drugs; pulmonary, cardiovascular and gastrointestinal effects of ecigarette use; the youth e-cigarette epidemic; how the JUUL device delivers nicotine and fosters youth addiction; the impact of JUUL flavors on youth use; the abuse liability of JUUL products; JLI marketing that attracted youth; nicotine treatment and cessation strategies for youth; and ecigarette youth prevention strategies. *Id.* at 167, et seq. Dr. Winickoff is not only uniquely qualified to offer expert testimony on these subjects by virtue of his unmatched credentials and experience in youth nicotine research, scholarship, policy and advocacy, as a practicing pediatrician he regularly treats numerous young patients struggling with nicotine addiction including many who became addicted as a result of JUUL. *Id.* at 11-14.

W. <u>Dr. Samuel Woolley</u>

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Dr. Samuel Woolley is an expert in how broadcast media, social media and emerging digital information communication technologies are used to influence human behavior. JLI Ex. 29, Woolley Rpt. at 1. Dr. Woolley is an assistant professor of journalism, media, and information at the University of Texas at Austin and the Fellow of the R.P. Doherty Professorship in Communication at UT Austin's Moody College of Communication--an endowed position. *Id.* He is also the head of the Propaganda Research Lab and a Knight Foundation Faculty Fellow at the Center for Media Engagement at UT. Id. Dr. Woolley has particular expertise in qualitative and open-source analysis of multi-faceted, multi-media influence campaigns run by corporations and others of the type that JUUL ran in this case. *Id.* He has researched and written extensively on the ways in which commercial marketing and advertising efforts have been translated to the digital sphere for a wide-variety of both transparent and opaque opinion-influencing campaigns. *Id.* His research and work on social media tools and strategies has been supported by large grants from the U.S. National Science Foundation (NSF) and the European Union's European Research Commission (ERC). *Id.* at 2. Dr. Woolley founded the Digital Intelligence Lab at the Institute for the Future in Palo Alto, CA where he worked with Fortune 500 companies to assess the dangers of digital information campaigns and he was the co-founder and Director of Research of the Computational Propaganda Project and the Oxford Internet Institute at the University of Oxford. Id. He has produced numerous highly-cited journal articles and book chapters on social media communication. *Id.* at 3.

Dr. Woolley is uniquely qualified to offer opinions on JUUL's coordinated online and offline campaigns to influence youth perceptions of its products. *Id.* at 5. This included seeding its marketing communications with young audiences so as to facilitate, amplify and co-opt usergenerated content to create the appearance of organic viral spread of popularity of the JUUL brand. *Id.* at 8, 12, 13, 17, 87, 88. Dr. Woolley explains in detail how, in JUUL's case, what ostensibly was user-generated content was often actually user-adopted content, with users adopting messaging seeded by JUUL or its proxies. *Id.* at 39-47. Dr. Woolley's opinions will significantly assist the jury in understanding the sophisticated and synergistic online and offline marketing strategies

planned and executed by JUUL and its proxies and the results of those strategies on young audiences. 2

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III. **LEGAL STANDARDS**

The Liberal Thrust of the Daubert Analysis A.

Under Federal Rule of Evidence 702, a qualified expert may testify if their opinion: (1) will "help the trier of fact to understand the evidence or to determine a fact in issue," (2) is "based on sufficient facts or data," (3) is "the product of reliable principles and methods," and (4) "reliably appl[ies] the principles and methods to the facts of the case." Fed. R. Evid. 702(a)-(d). Courts apply Rule 702 consistent with the "liberal thrust" of the Federal Rules of Evidence and their "general approach of relaxing the traditional barriers to 'opinion' testimony." Jinro Am. Inc. v. Secure Invs., Inc., 266 F.3d 993, 1004 (9th Cir. 2001) (quoting Daubert v. Merrell Dow Pharm., 509 U.S. 579, 588 (1993)). To that end, "[s]haky but admissible evidence is to be attacked by cross-examination, contrary evidence, and attention to the burden of proof, not exclusion." Murray v. S. Route Mar. SA, 870 F.3d 915, 925 (9th Cir. 2017) (citation omitted).

В. The Court's Broad Discretion to Assess Relevance And Reliability

The test for admissibility of expert testimony has two prongs: relevance and reliability. Daubert, 509 U.S. at 589. The "trial court must act as a 'gatekeeper' to exclude junk science that does not meet Federal Rule of Evidence 702's reliability standards by making a preliminary determination that the expert's testimony is reliable." Ellis v. Costco Wholesale Corp., 657 F.3d 970, 982 (9th Cir. 2011). But "the test under *Daubert* is not the correctness of the expert's conclusions but the soundness of his methodology." Torliatt v. Ocwen Loan Servicing, LLC, No. 19-04303, 2021 WL 5230755, at *2 (N.D. Cal. Nov. 8, 2021) (quoting *Primiano v. Cook*, 598 F.3d 558, 565 (9th Cir. 2010), as amended (Apr. 27, 2010)). There is no "strict checklist" of factors that courts are required to consider in a Daubert analysis, Desrosiers v. Flight Int'l of Fla. Inc., 156 F.3d 952, 961 (9th Cir. 1998), and courts are "entitled to broad discretion when discharging their gatekeeping function." United States v. Alatorre, 222 F.3d 1098, 1101 (9th Cir. 2000) (citation omitted).

1. Relevance is satisfied so long as there is a valid connection to the dispute.

Relevance "means that the evidence will assist the trier of fact to understand or determine a fact in issue." *Torliatt*, 2021 WL 5230755, at *2 (quoting *Cooper v. Brown*, 510 F.3d 870, 942 (9th Cir. 2007)). Stated differently, "[e]xpert opinion testimony is relevant if the knowledge underlying it has a valid connection to the pertinent inquiry." *City of Pomona v. SQM N. Am. Corp.*, 750 F.3d 1036, 1044 (9th Cir. 2014) (quoting *Primiano*, 598 F.3d at 565).

2. Reliability is a flexible determination based on the expert's qualification in the subject area and methodology.

To start, reliability requires that the expert's opinion have a "basis in the knowledge and experience of the relevant discipline." *Torliatt*, 2021 WL 5230755, at *2 (quoting *Primiano*, 598 F.3d at 565). One element of reliability is establishing the qualifications of an expert, which may be founded on the expert's "knowledge, skill, experience, training, or education." Fed. R. Evid. 702. As "long as the expert's testimony remains 'within the reasonable confines of his subject area,' it is admissible." *D.F. by & through Amador v. Sikorsky Aircraft Corp.*, No. 13-00331, 2017 WL 4922814, at *14 (S.D. Cal. Oct. 30, 2017) (quoting *Avila v. Willits Env't Remediation Tr.*, 633 F.3d 828, 839 (9th Cir. 2011)). With a proper foundation, an expert may be qualified in more than one area of expertise, including one that does not necessarily correspond to their principal education background. *See, e.g., Pooshs v. Phillip Morris USA, Inc.*, 287 F.R.D. 543, 553 (N.D. Cal. 2012) (admitting marketing testimony from an epidemiologist who had published research on tobacco product marketing).

To determine reliability, trial courts must also "assess the [expert's] reasoning or methodology" using the *Daubert* factors: "testability, publication in peer reviewed literature, and general acceptance [in the particular field]." *Primiano*, 598 F.3d at 564. Contrary to JLI's assertion that the *Daubert* standard is "stringent," Dkt. 2701 at 24 ("JLI Roadmap"), the Supreme Court and Ninth Circuit have repeatedly emphasized "that the 'test of reliability is 'flexible' and *Daubert*'s list of specific factors neither necessarily nor exclusively applies to all experts or in every case." *Primiano*, 598 F.3d at 564 (emphasis added).

Courts should not put undue weight on any individual factor but rather should "tak[e] into account the broader picture of the experts' overall methodology." *Wendell v. GlaxoSmithKline LLC*, 858 F.3d 1227, 1233 (9th Cir. 2017); *see also Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 151-52 (1999) (factors are "helpful, not definitive"). Nor does a "minor flaw in an expert's reasoning or a slight modification of an otherwise reliable method" render expert testimony inadmissible. *City of Pomona*, 750 F.3d at 1048 (alteration in original) (citation omitted). Where the methodology underlying the expert's opinion is sound, "the interests of justice favor leaving difficult issues in the hands of the jury and relying on the safeguards of the adversary system—
'[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof." *Wendell*, 858 F.3d at 1237 (alterations in original) (quoting *Daubert*, 509 U.S. at 596).

3. <u>Differing and Competing Expert Opinions Are Left for the Jury – The Trial Court Must Only Assess Methodology.</u>

The *Daubert* analysis focuses on the methodology underlying an expert's opinion, not the expert's conclusions. *Daubert*, 509 U.S. at 592, 597. *Daubert* requires the proponent of the scientific evidence to show that the expert's conclusion has been arrived at "in a scientifically sound and methodologically reliable fashion," not that the expert's opinion or methodology is beyond reproach. *In re Countrywide Fin. Corp. Mortg.-Backed Sec. Litig.*, 984 F. Supp. 2d 1021, 1036 (C.D. Cal. 2013).

Therefore, the focus of admissibility under *Daubert* is the reliability of the experts' methods, not the correctness of their conclusions. *Daubert*, 509 U.S. at 585. *See also Beech Aircraft Corp. v. Rainey*, 488 U.S. 153, 168 (1988); Fed. R. Evid. 402 In other words, it is not the trial court's task to decide whether an experts' conclusions are *correct. Daubert v. Merrell Dow Pharm., Inc.*, 43 F.3d 1311, 1318 (9th Cir. 1995) (*Daubert II*) ("[T]he Daubert test "is not the correctness of the expert's conclusion but the soundness of his methodology."). As long as the expert's testimony falls within "the range where experts may reasonably differ," then it is up to the jury to decide among the competing views. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 153, 119 S. Ct. 1167, 143 L. Ed. 2d 238 (1999).

4. Federal Rules of Evidence 703 and 403 Require Exclusion Only Where Impermissible Risk of Prejudice Cannot Be Cured With a Limiting Instruction.

Under Federal Rule of Evidence 703, an expert may "base an opinion on facts or data in the case that the expert has been made aware of or personally observed" and "if experts in the particular field would reasonably rely on those kinds of facts or data in forming an opinion on the subject, they need not be admissible for the opinion to be admitted." Fed. R. Evid. 703. However, "if the facts or data [that form an expert's opinion] would otherwise be inadmissible, the proponent of the opinion may disclose them to the jury only if their probative value in helping the jury evaluate the opinion substantially outweighs their prejudicial effect." *Id.* In particular, "the proponent may wish to disclose information that is relied upon by the expert in order to 'remove the sting' from the opponent's anticipated attack," and "[t]he trial court should take this consideration into account in applying the balancing test." *Id.* advisory committee's note. Likewise, "[o]therwise admissible expert testimony may be excluded under [Federal Rule of Evidence 403] if its probative value is substantially outweighed by the danger of unfair prejudice." *United States v. Hoac*, 990 F.2d 1099, 1103 (9th Cir. 1993).

In either case, the risk of unfair prejudice may be mitigated with a limiting instruction. *See* Fed. R. Evid. 403 advisory committee's note ("consideration should be given to the probable effectiveness or lack of effectiveness of a limiting instruction"); Fed. R. Evid. 703 advisory committee note ("In determining the appropriate course, the trial court should consider the probable effectiveness or lack of effectiveness of a limiting instruction under the particular circumstances."); *see also, e.g., United States v. Mende*, 43 F.3d 1298, 1302 (9th Cir. 1995) ("Any resultant prejudice was minimized by the limiting instruction.").

IV. OVERARCHING ISSUE

JLI contends that unspecified portions of Plaintiffs' experts' opinions must be excluded because the opinions are "preempted by federal law." (JLI Roadmap. at 20.) But JLI's argument is untethered to the principles of preemption (which the Court has already addressed numerous times in this litigation) *or* admissibility.

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As an initial matter, the Supremacy Clause "provides a 'rule of decision' for determining whether federal or state law applies in a particular situation" and does not govern the admissibility of expert testimony. *Kansas v. Garcia*, 140 S. Ct. 791, 801 (2020). JLI cites nothing that would connect a preemption and *Daubert* analysis. Instead, JLI simply asserts that "the federal regulatory scheme [] provides a *critical lens* through which the admissibility of expert testimony *must* be viewed" (JLI Roadmap at 3)—whatever that means. This "critical lens" is JLI's own creation and JLI cites no requirement or legal standard that the Court could even apply. *See Siqueiros v. General Motors LLC*, No. 16-cv-07244-EMC, 2022 WL 74182, at *1 (N.D. Cal. Jan. 7, 2022) (admissibility of expert testimony is governed by "the standards articulated in Federal Rule of Evidence 702 and *Daubert*"). The analysis can end here.

Even if the preemption were somehow relevant to the *Daubert* analysis, JLI's arguments concerning the preemptive effect of federal regulations are sorely misguided and inconsistent with this Court's prior orders. JLI spends pages discussing the proposition that the Tobacco Control Act² (the "TCA"), the Food, Drug, and Cosmetic Act³ ("FDCA"), and the Medical Devices Act⁴ ("MDA") create an exhaustive and preemptive web of regulation regarding the labeling, marketing and design of the JUUL product. (JLI Roadmap at 11-14). This presentation is inaccurate. As a threshold matter, JLI concedes that neither the MDA nor the FDCA actually apply to JUUL products. (JLI Roadmap at 14 ("JLI's products are not medical devices subject to regulation under the MDA"); *id.* (the FDCA "regulates cessation products . . . [which] is not the purpose or function of JUUL"). Inapposite statutes do not preempt claims (let alone evidence)). *C.f. ACA Connects v. Bonta*, No. 21-15430, 2022 WL 260642, at *7 (9th Cir. Jan. 28, 2022) ("[F]ederal agency may not preempt state regulation when the agency itself does not have regulatory authority").

This leaves only the TCA, which JLI contends preempts any expert testimony conflicting with either the FDA's toxicity labeling requirements or its "digital marketing guidance." (JLI

² Pub. L. No. 111-31, 123 Stat. 1776 (2009).

³ 21 U.S.C. §§ 301 *et seq*.

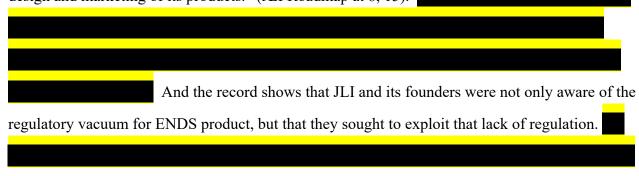
⁴ 21 C.F.R. §§ 820 et seq.

1	Roadmap at 12; 17; 19-20). Even if these preemption arguments are properly grafted onto a
2	motion to exclude, they directly conflict with this Court's determination that the TCA preempts
3	only a narrow set of claims based on nicotine addiction labeling. As to JLI's arguments
4	concerning the general breadth of the TCA, this Court already ruled that such broad field
5	preemption "is not contemplated by the text, history, and precedent under and in light of the
6	Congressional amendments to and extension of the Federal Food Drug, and Cosmetic Act
7	(FDCA) through the TCA." In re JUUL Labs, Inc., Mktg., Sales Pracs., & Prod. Liab. Litig., 497
8	F. Supp. 3d 552, 588 (N.D. Cal. 2020); see also id. at 594 ("[F]ield preemption is clearly not
9	contemplated by the structure of the TCA"). With respect to express preemption, the Court found
10	that claims based on the following were <i>not</i> expressly preempted: product liability (<i>id.</i> at 587);
11	product design (id. at 587); failure to provide warnings related to health risks (other than
12	addiction) on the product label (id. at 589); false and misleading statements on the product label
13	(id.); statements, omissions, or failures to warn on the JUUL website (id. at 590), and statements,
14	omissions, or failures to warn in JUUL marketing and advertising (id. at 590-91).
15	The Court's decisions were rooted in the narrow scope of the preemption provisions in the
16	TCA or applicable savings clauses. See Deeming Rule, 81 Fed. Reg. 28,973-01, 28,990 (May 10,
17	2016) ("Minimum Required Warning Statement is not intended to prevent tobacco product
18	manufacturers from including truthful, non-misleading warnings on their products' packaging or
19	advertisements voluntarily or as a result of FDA guidance."); 21 U.S.C. § 387p(a)(2)(B)
20	(excepting from preemption "requirements relating to the advertising and promotion of
21	tobacco products").
22	Pltf. Ex. 15, Henningfield Dep.
23	(Class) at 131:11-134:14.
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Id.⁵ In other words, there are no federal regulations that preempt the state law claims that Plaintiffs' experts offer opinions in support of. With respect to Plaintiffs' youth marketing claims, JLI provides no explanation for how such claims could possibly be preempted by regulations that purportedly concern product toxicity.

The only claims that the Court found were preempted were claims based on inadequate addiction warnings on the JUUL packaging itself. MTD Order I, 497 F. Supp. 3d at 589. Plaintiffs agree that their experts will not offer any opinions at trial suggesting the JUUL packaging should have included additional statements about addiction or that the FDA-mandated black box warning was insufficient. There is, therefore, no support for JLI's argument that Plaintiffs' experts' opinions must be excluded because they are offered in support of state law claims that are prohibited by the regulatory scheme governing tobacco products.

Putting aside JLI's misguided preemption framing, the crux of JLI's argument is that Plaintiffs' experts did not properly consider the impact of federal regulations on JLI's conduct. (JLI Roadmap at 8, 15-20, 26). According to JLI, this failure renders these expert opinions defective⁶ because the TCA regulatory scheme "infuses every decision JLI makes about the design and marketing of its products." (JLI Roadmap at 8, 15).



⁵ While the Court left open the possibility that issues of conflict preemption could arise in the future, it did not find any of Plaintiffs' current claims barred by conflict preemption. *Id.* at 593-94. And JLI's arguments identify no claims by any plaintiff group that would impose liability on JLI for taking or failing to take action that would have made it "impossible" to comply with applicable federal regulations. *See id.* at 592 (discussing the standards for conflict preemption).

⁶ Elsewhere in their brief, JLI alludes to the "lack of fit" standard, but does not elaborate on how Plaintiffs' experts' testimony is rendered irrelevant to the parties' dispute. (JLI Roadmap at 18). But in all events, Plaintiffs' expert testimony speaks directly to the disputed version of events that underlays this proceeding, and thus satisfies the fit requirement. *See Jones v. U.S.*, 933 F. Supp. 894, 900 (N.D. Cal. 1996), *aff'd*, 127 F.3d 1154 (9th Cir. 1997) (fit requirement is satisfied where evidence "speaks clearly and directly to an issue in dispute in the case").

Regardless of its merit, JLI's argument that Plaintiffs' experts did not *sufficiently* consider federal regulations as context for JLI's conduct goes to the weight of the expert's testimony, not its admissibility under Rule 702 or *Daubert. See, e.g., Planned Parenthood Fed'n of Am., Inc. v. Ctr. for Med. Progress*, 402 F. Supp. 3d 615, 719 (N.D. Cal. 2019) (rejecting exclusion and explaining that failure to account for variables in methodology or erroneous data "are, in the end, the sorts of issues that are appropriately used to discredit or undermine an expert on cross-examination"). JLI's reference to the Tennessee Products Liability Act does not change this analysis. (JLI Roadmap at 19-20). Even assuming JLI's analysis of Tennessee law is correct, it provides merely one factor for the jury to consider. An expert's failure to opine on a relevant factor is not a basis to exclude the expert's testimony. If such backdoor preemption arguments are permitted at trial, then JLI will be free to make its case to the jury that Plaintiffs' experts ignored what JLI sees as the "central concept of the TCA" and various other regulations. However, this argument—whether dressed up as preemption or not—supplies no basis for exclusion.

V. JLI MOTION #1: MARKETING

Plaintiffs' experts have strong credentials, as set forth in Section II above, and they did extensive research in developing their opinions. They carefully and methodically reviewed JLI documents, depositions, the scientific literature, ad campaigns and applied their extensive knowledge of marketing and/or youth nicotine addition to the facts of this case. Their opinions fit the facts of this case, will be extremely helpful to the trier of fact, and are, therefore, admissible.

JLI's attacks ignore the nature of, and foundation for, the experts' opinions. Rather than explaining why a particular opinion lacks reliability, JLI focuses on something the experts **did not** do, such as conducting a study. As described below, Plaintiffs' experts do not need to conduct their own studies to conclude that JUUL marketing appealed to youth and would have led a reasonable consumer to believe the products conveyed a safety message—there is ample information to support those conclusions. But even if these criticisms had merit, they go to the weight of the evidence and are fodder for cross-examination, not a basis to exclude the expert's testimony. The

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relevance of JLI's youth marketing to this litigation is clear and attacks on these opinions as irrelevant are likewise meritless.

There is, therefore, nothing irrelevant or unreliable about expert opinions stating that JLI's marketing appealed to youth, and that it caused young people to use the product. JLI's *Daubert* brief #1, addressed to youth marketing opinions, should be denied.

A. Admissible Marketing Opinions Do Not Require Studies

Through its marketing motion, JLI argues for the exclusion of unspecified portions of the opinions from numerous experts because the experts did not conduct formal consumer perception studies. See, e.g., JLI Mot. 1 at 5-9. But "the Ninth Circuit has upheld the admissibility of experts relying primarily on knowledge and experience rather than a particular methodology or technical framework." Cooper-Harris v. United States, No. 212CV00887CBMAJWX, 2013 WL 12125527, at *5 (C.D. Cal. Feb. 8, 2013). In Krommenhock v. Post Foods, LLC, 334 F.R.D. 552 (N.D. Cal. 2020), for example, the defendant sought to exclude the plaintiffs' consumer perceptions expert because the expert "conducted no consumer surveys or other tests, and instead relied on his own experience in the industry and its own documents." Id. at 579. This Court rejected the defendant's argument, describing it as "misplaced." Id. at 580. Previously, this Court held that "there is no per se requirement that all expert testimony be supported by empirical data." Fujifilm Corp. v. Motorola Mobility LLC, No. 12-CV-03587-WHO, 2015 WL 1737951, at *3 (N.D. Cal. Apr. 8, 2015). And, as here, when the area of expertise is a social science and "the research, theories and opinions cannot have the exactness of hard science methodologies, trial judges are given broad discretion to determine whether *Daubert*'s specific factors are, or are not, reasonable measures of reliability in a particular case." Golden W. Trading, Inc. v. BelGioioso Cheese, Inc., No. CV097803GHKAGRX, 2012 WL 12953447, at *1 (C.D. Cal. Apr. 16, 2012) (quoting *United* States v. Simmons, 470 F.3d 1115, 1123 (5th Cir. 2006)) see also Price v. L'Oreal USA, Inc., No. 17 CIV. 614 (LGS), 2020 WL 4937464, at *5 (S.D.N.Y. Aug. 24, 2020) (stating that "expert reports regarding consumer perception need not be based on scientific surveys," and that "experts may testify based on their own experience"). JLI does not cite any authority excluding a marketing

expert's opinion for failure to conduct a formal study. At best, JLI's arguments go to weight, but not admissibility.

The key issue for *Daubert* is whether the expert's opinion is based on "good grounds," not whether some other type of evidence might have been more persuasive. In re Countrywide Fin. Corp. Mortg.-Backed Sec. Litig., 984 F. Supp. 2d 1021, 1036 (C.D. Cal. 2013). And as this Court has held, "even in the age of *Daubert* and *Kumho*, experience-based experts may testify on matters within their expertise." United States v. Bazaarvoice, Inc., No. 13-CV-00133-WHO, 2014 WL 11297188, at *2 (N.D. Cal. Jan. 21, 2014) (citing Fortune Dynamic, Inc. v. Victoria's Secret Stores Brand Mgmt., Inc., 618 F.3d 1025, 1043 (9th Cir. 2010) (admitting proffered expert's industry testimony where his expertise "is one based on experience")). This is particularly true in matters of social science. See NAACP v. City of Myrtle Beach, 504 F. Supp. 3d 513, 517 (D.S.C. 2020) (stating that in the social sciences field "experience is the predominant, if not sole, basis for a great deal of reliable expert testimony"). In *Post Foods*, for example, the Court permitted an expert to offer opinions that marketing messages "conveyed a health message" without the use of studies and based primarily on the expert's experience. 334 F.R.D. at 579-80.

JLI's arguments also ignore that Plaintiffs' experts have relied on studies conducted by others; have conducted their own empirical work; and where necessary, have explained why the type of empirical studies demanded by JLI are not practical in this setting. See Section V.D., infra. Instead of addressing these opinions head-on, JLI simply declares that the experts have not conducted sufficient studies. Such cursory statements cannot support the wholesale exclusion of expert opinions.⁷

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⁷ JLI asks this Court to prevent experts from offering testimony without identifying the specific opinions to be excluded. By filing motions that make broad, sweeping arguments that amount to nothing more than credibility challenges, JLI asks this Court to speculate and make advisory rulings on nearly every issue in the case. Courts, including MDL Courts, have rejected similar efforts. In re Ethicon Inc. Pelvic Repair Systems Product Liability Litigation, 2017 WL 1175377, *5 (S.D.W. Va., Mar. 29, 2017) (declining to exclude testimony where the party seeking exclusion does not provide specific content or context); In re Bard IVC Filters Products Liability Litigation, 2017 WL 6554163, *3 (D. Ariz., Dec. 22, 2017); Bernal v. Daewoo Motor America, Inc., 2011 WL 13183093, at *1 (D. Ariz., Aug. 31, 2011) (declining to exclude expert where the party has not identified with precision the opinions to be excluded but merely asks the Court to exclude testimony on biomechanics).

B. <u>Plaintiffs' Experts Provide Reliable Opinions Regarding Consumer</u> Perceptions of the Health Effects of JUUL

JLI's challenges to the opinions of Plaintiffs' experts about consumer perceptions of JUUL's health effects are without merit (JLI Mot. 1 at 5-9).

JLI seeks to exclude the opinions of Drs. Pratkanis, Jackler, and Grunberg because they did not conduct formal consumer perception studies. (*Id.*) But, as noted above, studies are not a prerequisite to admissibility under *Daubert*. *See* Section V.A., *supra*. Plaintiffs' experts did, however, consider and assess empirical research available to them in the record, including in Defendants' own documents. *See*, *e.g.*, JLI Ex. 17, Pratkanis Rpt. at 13 (

They also relied of well-accepted methodologies in the field of social science. Dr. Pratkanis, for example, analyzes JUUL marketing through the widely-accepted principles of a "unique selling proposition" (USP). *Id.* at 7-13. He further analyzes likely consumer takeaways from the USP through widely accepted research on "implicit conversation norms" and "schematic processing." *Id.* at 11-14.

JLI's argument that "experience alone" is insufficient is wrong for several reasons, and the cases it cites are inapposite. In *GPNE Corp. v. Apple, Inc.*, 2014 WL 1494247 (N.D. Cal. Apr. 16, 2014), an expert employed no methodology to arrive at a mathematical conclusion. *Id.* at *4 (deriving a \$1 per unit royalty from an \$86 incremental net profits). That situation has no bearing on the standards for reliable social science opinions.

also contends that unspecified experts failed to consider "critical context" regarding "public health policies." (JLI Mot. 1 at 5). JLI again cites no authority in support of its argument. Nor does it explain why the experts need to consider health policies when offering opinions concerning how consumers perceive JUUL's actual marketing. JLI's argument instead seems to be another effort to baselessly preclude Plaintiffs' claims based on vague references to regulations.

Pratkanis: JLI argues that Dr. Pratkanis is not "trained or experienced in marketing," (JLI Mot. 1 at 6), but cites nothing in support of that proposition. Dr. Pratkanis's areas of research and

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study include "mass communications, deceptive advertising, sales practices, and economic fraud" (JLI Ex. 17, Pratkanis Rpt. at 1). JLI also argues that the trier of fact may not agree with Dr. Pratkanis's opinions. (JLI Mot. 1 at 6). But the jury always has the ability to disagree with *any* expert and that is, of course, not a basis for exclusion. *See Scripps Health v. nThrive Revenue Sys.*, *LLC*, No. 19-CV-00760-H-DEB, 2021 WL 3372835, at *7 (S.D. Cal. May 10, 2021) (stating that "disagreement with an expert's opinion is not a basis for exclusion").

With respect to Dr. Pratkanis's USP opinions, JLI states that his approach is "backwards and subjective" and "contrary to authorities" that Dr. Pratkanis relies on, but provides no elaboration, citation, or support. (JLI Mot. 1 at 6). An expert cannot be excluded based on such threadbare attacks. JLI's other arguments are equally flawed. First, as noted above, admissibility does not turn on whether an expert conducted a study. Second, Dr. Pratkanis does not opine that "all consumers" (JLI Mot. 1 at 6) would have had the same perception of JUUL marketing; he instead focused on a "typical, reasonable consumer." See JLI Ex. 17, Pratkanis Rpt. at 1. Third, the holding in FTC v. DIRECTV, Inc., 2018 WL 3911196 (N.D. Cal. Aug. 16, 2018), does not support the exclusion of Dr. Pratkanis's testimony. The judge in FTC permitted Dr. Pratkanis's opinions but ultimately did not rely on them in ruling after a bench trial. The court concluded that Dr. Pratkanis "did not analyze Defendant's advertisements to determine their net impression, or do any content analysis that would support the conclusion that his conclusions were generalizable to all of the ads at issue over the eight-year period at issue." *Id.* at *11. But here, Dr. Pratkanis has done all those things in developing his opinions, and he concluded that a common unique selling proposition runs throughout JUUL's marketing campaigns. See JLI Ex. 17, Pratkanis Rpt. at 23-55. In doing so, he examined the content and themes of various marketing campaigns. *Id.* Nothing in FTC undermines the general reliability of Dr. Pratkanis's overall USP approach, and other courts have admitted and found persuasive Dr. Pratkanis's marketing testimony. See State v. LA Investors, LLC, 410 P.3d 1183, 1190, 1195–96 (Wash. Ct. App. 2018); People v. Johnson & Johnson, No. 37201600017 229CUMCCT, 2020 WL 603964, at *22 (Cal. Super. Jan. 30, 2020) (discussing "credible testimony from Dr. Pratkanis that by emphasizing the risks of the implantation procedure, J&J's marketing minimizes the risks specific to the mesh implant itself."); State v. Living

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Essentials, LLC, No. 14-2-19684-9 SEA, 2016 WL 7493639 (Wash. Super. Dec. 02, 2016) (finding that Dr. Pratkanis "testified credibly that the clear takeaway from these ads was that 'doctors would recommend' 5-Hour ENERGY").

Jackler: Dr. Jackler's opinions mainly concern Plaintiffs' youth marketing claims, and not Plaintiffs' health risk marketing claims. Therefore, it is unclear what opinions about "Consumer Perception of JUUL Toxicity or Addictiveness" JLI seeks to exclude, and JLI does not point to any. In any event, as with Dr. Pratkanis, JLI makes the legally unsupportable argument that Dr. Jackler's opinions should be excluded because he did not conduct or cite a consumer perception study. (JLI. Mot. 1 at 7.) JLI also fails to explain why a study Dr. Jackler cites regarding health effects messaging in cigarette advertising is irrelevant. The study concerned how terms such as "alternative" and switch" have been shown to a message of "health reassurance," which supports Dr. Jackler's opinions concerning how consumers would perceive JUUL advertising that used highly similar terminology, even if the study does not directly concern JUUL or ENDS products. See JLI Ex. 40, Jackler Dep. at 250:5-18. If JLI believes that such studies have little probative value because they did not specifically address JUUL marketing, that is an argument that goes to the study's weight, and is fodder for cross-examination, not a basis for exclusion.

There are only two portions of Dr. Jackler's report that JLI addresses explicitly,⁸ and neither should be excluded. First, with respect to Dr. Jackler's comparison between JUUL and cigarette marketing,⁹ JLI argues that this is Dr. Jackler's subjective assessment and that there is no research on consumer perceptions. As to the former argument, Dr. Jackler has decades of experience in the field of tobacco advertising, is published in the field, and is the founder of Stanford Research Into the Impact of Tobacco Advertising ("SRITA") (JLI Ex. 11, Jackler Rpt. at 9-11). He is well-

⁸ Citing page 59 of Dr. Jackler's report in a footnote, JLI asserts that Dr. Jackler is not qualified to opine on FDA regulations. Nothing in the cited portion of Dr. Jackler's report refers to FDA regulations.

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qualified to offer opinions concerning similarities between JUUL and cigarette marketing. As to the latter, as noted, consumer perception opinions do not require studies.

Second, JLI seeks to exclude unspecified portions of Dr. Jackler's opinions because of the purported unreliability of his published article "JUUL Advertising Over Its First Three Years on the Market." (JLI Mot. 1 at 8). It is unclear why JLI focuses on this article in its challenges to Dr. Jackler's health messaging opinions; the article is only in three places in the Report, none of which discuss consumer perceptions of toxicity or addictiveness. *See* JLI Ex. 11, Jackler Rpt. at 11, 278, 421 (citing article). There is thus no basis to exclude any opinions that cite to "JUUL Advertising Over Its First Three Years on the Market" as improper opinions concerning "Consumer Perception of JUUL Toxicity or Addictiveness."

Grunberg: JLI seeks to exclude unspecified portions of Dr. Grunberg's opinions because he purportedly lacks experience to opine on marketing issues. (JLI Mot. 1 at 9.) But Dr. Grunberg does not opine on marketing generally. In pages 104 through 125 of Dr. Grunberg's report (which Plaintiffs assume is what JLI's motion is targeted to, because JLI does not specify), he offers opinions concerning how JUUL marketing and product design "increase the abuse liability of JUUL, especially by youth and adolescents." See JLI Ex. 8, Grunberg Rpt. ¶ 253. These opinions concern the intersection of product marketing and consumer behavior, especially in the area of nicotine use, and are well within Dr. Grunberg's training as a clinical phycologist with extensive experience in the area of behavioral health as it concerns tobacco products. *Id.* ¶¶ 5-8. Dr. Grunberg has served in leadership roles in a number of organizations that focus on youth usage of tobacco products. Id. ¶ 9. He has written extensively on issues related to adolescent tobacco use. Id. ¶ 11. He has "studied and taught about cigarette advertising and effects of advertising on youth and adult smoking for more than 40 years." Id. ¶ 15. While a marketing degree might be important when designing an overall marketing strategy, it is not needed to evaluate the likely behavioral impacts of marketing on certain target populations. See CSL Silicones, Inc. v. Midsun Group Inc., 2017 WL 6055380, at *2 (D. Conn. Dec. 7, 2017) ("One may become qualified as an expert based on practical experience, so that professional education is not a prerequisite.").

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None of JLI's remaining scattershot arguments supports excluding any of Dr. Grunberg's opinions. As a threshold matter, Dr. Grunberg's marketing and product appeal opinions focus on youth appeal, not toxicity or health messaging (See JLI Ex. 8, Grunberg Rpt. ¶ 253 (summary of opinions)), and it is thus unclear what JLI seeks to exclude in this section of its brief. Setting that aside, JLI's arguments do not raise *Daubert* issues. While JLI asserts that bright colors and shapes do not convey health messages, this is simply a disagreement with Dr. Grunberg's conclusions. And while JLI claims that Dr. Grunberg applied no "scientific principles," his opinions are based on decades of research and his own experience. In his deposition, Dr. Grunberg made clear that this experience—which underlies his opinions—is based on "principles of persuasive communication, particularly within social psychology, the influence of peer pressure, social influence, information presentation." See JLI Ex. 37, Grunberg Dep. at 43:21-44:7. Dr. Grunberg discussed the historical research on the relationship between tobacco advertising and products in, among other places, the Appendix in his report. See JLI Ex. 8, Grunberg Rpt. App'x at 37-42. Lastly, it is immaterial that Dr. Grunberg did not recall specific post-Vaporized campaigns during his deposition. His report focuses on Vaporized. See Id. ¶ 260-73. In terms of the long-term impact of Vaporized, he explained that "the movement towards influence on kids would have to do with the early information, and then the information as it got out on social media" JLI Ex. 37, Grunberg Dep. at 67:3-6. And, his opinions concerning youth appeal are based on much more than product imagery; they are based on product design, flavors, and accessibility. JLI Ex. 8, Grunberg Rpt. at ¶¶ 254-85.

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C. The Experts' Opinions that JUUL Marketing Appealed to Youth are Well Supported by the Record and the Scientific Literature, and JLI's Arguments Provide No Basis to Exclude Any Opinions at Trial.

This Court should reject JLI's arguments attacking the relevance and reliability of multiple experts' opinions about JLI's youth marketing. This section responds to pages 10-28 of JLI's Brief #1. Instead of attacking the experts' actual opinions, JLI proposes different analyses that the experts might have done. These are issues for cross-examination.

Below, Plaintiffs will first explain the history of JLI's marketing to youth, as told by Plaintiffs' experts. This history will give the Court context to evaluate JLI's attacks. The legal

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context is also important. To the extent JLI contends that opinions about youth marketing are irrelevant, such arguments defy logic. Youth marketing plays a key role, in any personal injury case involving a Plaintiff who started using JUUL as a child; in the government entity cases that allege damages to school districts; and in the class case that seeks restitution for the unfair marketing of JUUL to underage persons. As to reliability, JLI's argument contradicts conclusions by the FDA and the Surgeon General, among others, who have laid the blame for the youth vaping epidemic squarely at JLI's feet.

The experts' opinions about JLI's youth marketing are relevant and reliable.

1. There is Ample Evidence That JLI's Marketing was Appealing to Adolescents, as Plaintiffs' Experts Opine

Several Plaintiffs' experts address JLI's—and the other Defendants'—marketing of JUUL to youth. These opinions explain how JLI appealed to youth through expertly planned and executed advertising campaigns such as Vaporized and Save Room for JUUL, the unique design of the JUUL product, the marketing channels used, and JLI's extensive efforts to drive "viral" social media marketing.

See JLI Ex. 5, Drumwright Report at 132; JLI Ex. 11, Jackler Report at 132-48; JLI Ex. 3, Chandler Report at 9.

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Ex. 5, Drumwright Report at 104 (quoting U.S. Surgeon General's advisory).

Early JUUL advertising campaigns such as Vaporized and Save Room for JUUL had young models and additional elements that appealed to adolescents. Further, the product appealed to youth. JUUL could be easily hidden, would light up in "party mode," and had fun flavors such as mint and mango. All of these factors drove sales among underage adolescents, as laid out below.

a. **JUUL Advertising Campaigns**

JLI followed many of the tactics used by the traditional cigarette industry before the Master Settlement Agreement ("MSA") curtailed their youth marketing. *See, e.g.*, JLI Ex. 5, Drumwright, Rpt. at 80-81; JLI Ex. 7, Emery Rpt. at 10-11; JLI Ex. 8, Grunberg Rpt. at 90-92 (JLI used flavors

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because	flavors appealed to youth); JLI Ex. 10, Halper-
Felsher Rpt. at 62-64; JLI Ex. 17, Pratkanis Rpt. at	104; JLI Ex. 25, Winickoff Rpt. at 10-11 (JLI's
manipulation of nicotine for smoother hit is "a play	out of the old tobacco industry playbook"); JLI
Ex. 11, Jackler Rpt. at 18, 53.	

One such approach was using billboard advertising. The first major JUUL ad campaign was called Vaporized, featuring both roadside billboards in select cities and massive digital billboards in Times Square. See JLI Ex. 3, Chandler Rpt. at 23-24; JLI Ex. 11, Jackler Rpt. 126-29. The campaign began in New York and Los Angeles but spread across the country through print, digital, and programmatic digital advertising. See JLI Ex. 11, Jackler Rpt. at 132. The Vaporized campaign utilized young-looking trendy models, in fun, dynamic poses with bright-bold colors. See JLI Ex. 11, Jackler Rpt. at 363; JLI Ex. 17, Pratkanis Rpt. at 26-29; JLI Ex. 7, Emery Rpt. at 15-16. JLI also placed Vaporized ads at retail locations such as convenience stores, which are frequently visited by adolescents. See JLI Ex. 7, Emery Rpt. at 17; JLI Ex. 11, Jackler Rpt. at 375. For example, JLI placed convenience store and gas station counter-displays, near the check-out register next to candy and bubble gum, throughout the United State which played a looping video of the Vaporized models having fun and dancing with JUUL:



See JLI Ex. 11, Jackler Rpt. at 245-48-; JLI Ex. 7, Emery Rpt. at 17-19; JLI Ex. 5, Drumwright, Rpt. at 20-22; JLI Ex. 17, Pratkanis Rpt. at 29. Thus, millions of eyeballs were on the campaign, and even JLI executives realized the models looked too young.

See JLI Ex. 5, Drumwright Rpt. at 94

Another early JUUL campaign, Save Room for JUUL, normalized vaping by showing JUUL devices paired with food. JLI hired chefs to create food pairings for JUUL, evoking the idea that JUUL was a dessert. See JLI Ex. 11, Jackler Rpt. at 98-100. After that campaign, JLI continued that concept in its social media marketing, displaying flavored JUULs with food representing the flavor. See JLI Ex. 8, Grunberg Rpt. at 121. The psychology of using food is to "teach youth to associate JUUL with harmless stimuli such as food or scenery and, eventually, put youth at risk of developing positive perceptions of JUUL." Id. at 119. The bright colors in these ads were another way that JLI appealed to young people. Id. at 110.

b. "Viral" Social Media Marketing

JLI's early campaigns set the stage for its huge marketing push that drove the youth vaping
epidemic: viral social media marketing. JLI seeded this effort with its early ad campaigns, launch
parties, , and "hashtagging"
on various social media platforms, among other strategies. JLI's social media dominance did no
happen by accident—it was planned. JLI Ex. 10, Halpern-Felsher Rpt. at 133-34. Marketing or
social media inherently markets substantially to children, as they make up a disproportionate share
of social media users. <i>Id.</i> at 79-87.

In 2015, JLI hosted special events where attendees could socialize, try JUUL, and hopefully (from JLI's perspective) spread the word about the product. The first JUUL "launch party" in June 2015 resulted in the following statistics:

JLI Ex. 3, Chandler Rpt. at 13. JLI did not exclude youth from these events, as evidenced by the presence of a 17-year-old high school student at the JUUL launch party. She tweeted about the event, and JUUL "liked" her tweets to amplify the message. *Id.* at 16-22.

Influencers were a huge part of JLI's social media campaign, as seen in JLI's internal documents and depositions. *See, e.g.*, JLI Ex. 10, Halpern-Felsher Rpt. at 99-107.

JLI Ex. 7, Emery Rpt. at 44. Some of the influencers were young themselves, such as , who promoted JUUL at age 17. *Id.* at 47-48. JLI also used celebrity influencers who had large audiences among teens. *Id.* at 46. For instance, Katy Perry had more than 90 million followers on Twitter and 51 million on Instagram, social media platforms that skew young. JLI Ex. 5, Drumwright Rpt. at 63, 74. According to JLI's documents, its celebrity influencer program generated a social media reach of and an "earned media" reach of in 2017 alone. JLI Ex. 10, Halpern-Felsher Rpt. at 122; JLI Ex. 11, Jackler Rpt. at 197-223.

JLI also took direct action on social media to advertise. JLI had corporate accounts on Instagram, Twitter, Facebook, and YouTube, all of which are popular among adolescents. JLI Ex.

10, Halpern-Felsher Rpt. at 87. Hashtags such as #JUUL and #juulvapor were pervasive on social media platforms such as Twitter and Instagram. *Id.* at 120-21. JUUL hashtags amplified JUUL's own advertising and encouraged users to create their own hashtags, further expanding the reach of JUUL's social media content. JLI Ex. 11, Jackler Rpt. at 162-72; JLI Ex. 7, Emery Rpt. at 52. Thanks to JLI's efforts, the number of JUUL-related tweets exploded between early 2017 and the end of 2018. JLI Ex. 7, Emery Rpt. at 56. The number of JUUL tweets strongly correlated with JUUL's retail sales, as both increased exponentially over that period. *Id.* at 57.

c. Product Design

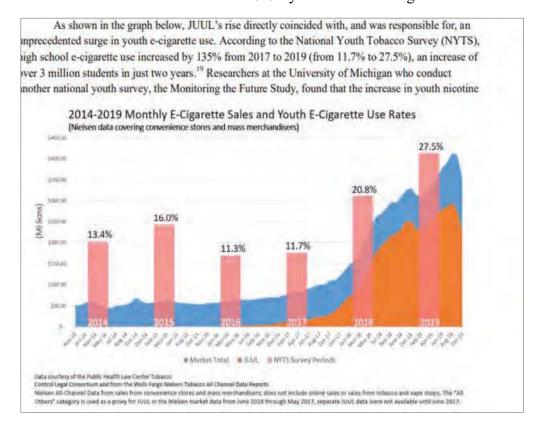
JUUL's design further enhanced its appeal to adolescents. From the beginning, JLI billed itself as a "lifestyle" company or a tech company, not a nicotine company. JLI Ex. 11, Jackler Rpt. at 27-28; JLI Ex. 5, Drumwright Rpt. at 14, 17. The JUUL device is small, easily concealed, and looks like a flash drive—not a cigarette. JLI Ex. 8, Grunberg Rpt. at 106; JLI Ex. 11, Jackler Rpt. at 20. Responding to a survey conducted by Dr. Halpern-Felsher, users identified JUUL being easy to hide as one of best attributes. JLI Ex. 10, Halpern-Felsher Rpt. at 76. One of JLI's goals was to create a device that was "

"JLI Ex. 17, Pratkanis Rpt. at 15. Some compared the high-tech JUUL device to the iPhone. JLI Ex. 5, Drumwright Rpt. at 15.

Other features that appealed to youth included the use of nicotine salt vapor formula that is less harsh than a traditional cigarette, and the use of sweet and fruity flavors such as mango and crème brulee. *Id.* at 159. As seen in the scientific literature, flavors appeal to youth because they mask the harsh taste of tobacco, and the use of flavors has been linked to a rise in youth e-cigarette use. JLI Ex. 11, Jackler Rpt. 293-296; JLI Ex. 10, Halpern-Felsher Rpt. at 39-41. When JLI sought FDA approval for JUUL in 2020, its first item under the heading "was "as "Pltf. Ex. 3, PMTA Submission to FDA at 91. The device also would light up in "party mode," which appealed to youth. JLI Ex. 10, Halpern-Felsher Rpt. at 54-55; JLI Ex. 11, Jackler Rpt. at 20).

d. <u>Effectiveness of Youth Marketing</u>

The result of JLI's marketing efforts is clear. As JUUL sales exploded, so did youth vaping, as seen in this chart submitted to the FDA in 2019 by several health organizations:



JLI Ex. 10, Halpern-Felsher Rpt. at 163.

While JLI attacks the opinion that its marketing appealed to youth, Plaintiffs' experts are not alone in reaching this conclusion. For instance, the aforementioned letter to the FDA noted that "JUUL's role in the youth vaping epidemic has been stated by numerous health and governmental organizations including the FDA and CDC." *Id*.

JLI Ex. 5.

Drumwright Rpt. at 136-37. Years later, the head of the FDA, Scott Gottlieb, stated that he hoped JLI realized that "the problem that's been created has been created largely by their product." JLI Ex. 11, Jackler Rpt. at 392. In 2021, Interim FDA Director Janet Woodcock, laid responsibility for the youth vaping epidemic directly at the feet of JLI:



FDA interim chief,
Janet Woodcock said
last week it appears
that JUUL was the
e-cigarette company
most responsible for
creating this epidemic.

https://www.bloomberg.com/news/articles/2021-06-23/fda-chief-ties-e-cigarette-maker-to-nicotine-addiction-in-kids

JLI Ex. 11, Jackler Rpt. at 386, n.262, 392.

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Ex. 5, Drumwright Rpt. at 95-96.

2. None of JLI's Attacks on Plaintiffs' Experts are Meritorious, and all Raise Issues Nothing More than Credibility Issues for Cross-Examination, not Grounds for Exclusion of any Opinions

The foregoing analysis—which represents only a small portion of the analysis contained in the experts' reports—is derived from JLI's documents, depositions of JLI officers, the scientific literature, statements of government bodies such as the FDA, and the experts' own knowledge and experience.

For the most part, JLI does not attack specific expert opinions or the evidence that supports them. JLI is not, for instance, arguing that Plaintiffs" experts are misquoting their sources, or that JLI's documents do not accurately reflect its activities. Nor does JLI explain how it is unreliable to opine that JLI's marketing was youth-focused when there is clear consensus that JLI's marketing was youth-focused. While *Daubert* removed general acceptance as the primary criterion for admissibility, it remains an important consideration. *Daubert v. Merrell Dow Pharms.*, *Inc.*, 509 U.S. 579, 594 (1993). Here, the scientific consensus is that JLI's advertising appealed to youth. *See* JLI Ex. 10, Halpern-Felsher Rpt. at 163 (letter to FDA).

The other key point in considering JLI's attacks is that Plaintiffs' experts are true leaders in their field. *See generally*, Section II, *supra* (describing expert qualifications). For instance, Dr. Prochaska is Director of Stanford University Cancer Center's Tobacco Treatment Service,

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where she treats patients suffering from nicotine addiction, including JUUL users. JLI Ex. 18, Prochaska Rpt. at 1-2. Dr. Jackler is a medical doctor who has studied tobacco marketing and addiction for more than 15 years, and has published in the field. JLI Ex. 11, Jackler Rpt. at 9. Dr. Chandler is a marketing professor who previously worked for the largest digital marketing agency in the world, and has specialized expertise in the types of campaigns that JLI ran. JLI Ex. 3, Chandler Rpt. at 3-4. Dr. Halpern-Felsher is a Stanford professor and developmental psychologist who specializes in adolescent and young adult risk management, including tobacco addiction. JLI Ex. 10, Halpern-Felsher Rpt. at 2-3.

These are only a few examples of how well-qualified Plaintiffs' experts are, and those qualifications also support the reliability of their opinions. *See*, *e.g.*, *NAACP*, 504 F. Supp. 3d at 517 (stating that in the social sciences field "experience is the predominant, if not sole, basis for a great deal of reliable expert testimony" (citing Fed. R. Evid. 702 advisory committee's note to the 2000 amendments)); *Bazaarvoice*, *Inc.*, 2014 WL 11297188, at *2 (N.D. Cal. Jan. 21, 2014) (holding that "experience-based experts may testify on matters within their expertise"). JLI's attacks offer material for cross-examination, not grounds for exclusion, as laid out below.

a. Unable to Attack the Experts' Actual Opinions, JLI Tries to Argue That They Should Have Taken Other Steps in Developing Their Opinions.

JLI completely misconstrues the *Daubert* standard. Rather than addressing the experts' opinions or evidence, as summarized above, JLI attacks the experts for failing to create or consider other evidence. JLI argues, apparently, that more than a dozen experts should be excluded from testifying entirely because they did not conduct a survey about how youth reacted to advertisements, relied on their own impressions of the ads, and failed to compare and contrast JLI's various advertising campaigns. (*See* JLI Mot. 1 at 10-16).

i) <u>Claims That an Expert Should Have Considered Other</u> <u>Evidence are for the Jury.</u>

To the extent JLI argues that Plaintiffs' experts should have conducted some additional research or analysis—i.e., conducting a survey or analyzing all of JLI's ad campaigns—that is fodder for cross-examination, not a basis for exclusion. As noted above (*see* Section V.A., *supra*),

the law is clear that a study or other empirical data is not required to give a reliable opinion about advertising campaigns. Applying these principles, a recent federal decision rejected the type of argument that JLI makes here. The court noted that "[m]any matters related to reliability have been found to [be] the subject of cross-examination rather than grounds for exclusion." *United States v. Evers*, No. 3:19-CR-250, 2021 WL 3710735, at *10 (M.D. Pa. Aug. 20, 2021). The court added that the failure to consider alternative evidence is not a basis for exclusion, noting that a party "may probe what materials were not reviewed on cross-examination and may challenge an expert's conclusions by referencing evidence not taken into consideration." *Id.* That same principle applies here.

b. <u>JLI's Arguments Provide no Basis to Exclude any Expert's Opinions.</u>

Ignoring the legal principles cited above, JLI attacks Plaintiffs' experts for what they supposedly failed to do. JLI claims these experts' opinions should be excluded because they failed to conduct studies, relied on observations over data, and/or failed to consider all of JLI's marketing campaigns. (JLI Mot. 1 at 10-16). None of these arguments have merit.

As discussed above, conducting surveys was unnecessary to form reliable opinions about JUUL, given the real-world data available. JLI's motion cherry-picks quotations in trying to argue that surveys were required while ignoring the experts' explanations for the approaches they took. For instance, Dr. Emery explained that it is "exceedingly difficult to do that research about how [advertising is] perceived in a real-world setting." JLI Ex. 36, Emery Dep. at 175:20-176:2. Dr. Grunberg explained that he assessed JLI's advertisements using scientific principles that have been established since the 1950s, including persuasive communications, social psychology, influence of peer pressure, social influence, and information persuasion. JLI Ex. 37, Grunberg Dep. at 43:23-44:22. As Dr. Jackler noted, what transpired in the real world was a "natural experiment":

Many phenomena are studied based upon what actually happened. So you look at what happened in the marketplace, and that is an example of studying what actually occurred in response to the advertising and the promotion So that can be looked at ... scientifically as a natural experiment based upon the rise in youth use and what the drivers of youth use were.

JLI Ex. 40, Jackler Dep. at 89:25-90:17. The real-world data are the true "experiment" as to whether JLI's marketing appealed to youth. *See* JLI Ex. 34, Drumwright Dep. at 74:23-75:8 ("I didn't need to [conduct a study] because there was such an abundance of data that had already been collected by JUUL, by Altria, by their consultants."); *see also* JLI Ex. 54, Winickoff Dep. at 207:7-208:3 (explaining his use of statistical analysis from the Surgeon General and CDC).

JUUL ads. (JLI Mot. 1 at 11-13).

JLI Ex. 5, Drumwright Rpt. at 94 (quoting a 2016 JLI document as stating that

That statement says far more about how Vaporized was perceived when it ran than any survey could do in 2021 or 2022.

JLI also criticizes Dr. Woolley for stating that his interpretation is not replicable, but as he and other experts have testified, not all scientific research is replicable. *See* JLI Ex. 56, Woolley Dep. at 368:14-21 ("There are some methods of qualitative social science that do replication. Field research methods done ... in this context would not be replicable. And ... social scientists in this context would expect that."); JLI Ex. 54, Winickoff Dep. at 100:4-13 (explaining that certain qualitative research and meta-analyses do not fall into the category of being "objective and repeatable")).

Further, to the extent they are relying on their own perceptions in evaluating JLI's advertisements, the experts are not violating any *Daubert* principles. *See Post Foods*, 334 F.R.D. at 580 (allowing expert's opinions about marketing campaign based on his many years of marketing experience and his review of Kellogg's own internal consumer research and other documents"); Fed. R. Evid. 703 ("An expert may base an opinion on facts or data in the case that the expert has been made aware of or personally observed."); *In re: Tylenol (Acetaminophen) Marketing, Sales Practices and Products Liability Litigation*, 2016 WL 807377, at *1 (E.D. Pa., Mar. 2, 2016, No. 2436) (allowing expert's opinion about marketing campaign based on his experience, and review of images from the campaign, internal documents and company depositions). Clearly, images are

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a huge part of advertising, so Plaintiffs' experts would be evaluating images in the real world. *See*, *e.g.*, JLI Ex. 3, Chandler Rpt. at 24 (showing JUUL billboards); JLI Ex. 46, Pratkanis Dep. at 213:2-5 (agreeing that JLI's images and message have created a norm that consuming nicotine "is cool or okay or acceptable"). One touchstone of the *Daubert* inquiry is ensuring that experts take the same approach to litigation that they would take in the real world. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999). Plaintiffs' experts have done that here.

Meanwhile, JLI's argument that the experts needed to compare all JUUL campaigns is a red herring. (*See* JLI Mot. 1 at 13-16). Plaintiffs' experts are not opining that every aspect of JLI's marketing appealed to youth. As laid out above, the experts generally focus on early ad campaigns such as Vaporized and Save Room for JUUL, as well as JLI's pervasive marketing on social media. *See, e.g.*, JLI Ex. 3, Chandler Rpt. at 9-80 (describing JLI's digital/social media campaign, including Vaporized); JLI Ex. 11, Jackler Rpt. at 36-100 (describing the Vaporized and Save Room for JUUL campaigns). Some experts also addressed other campaigns, such as Make the Switch. *See, e.g.*, JLI Ex. 11, Jackler Rpt. at 100-15. Again, in claiming that certain experts should have analyzed additional campaigns, JLI is advocating for a different analysis, rather than criticizing the one actually given—and that is an issue for cross-examination, not a basis for exclusion. *Evers*, 2021 WL 3710735, at *10.

JLI's meandering argument also attacks experts' alleged failure to do any "quantitative analysis" regarding the youth appeal of its advertising. But as Dr. Chandler points out, when JLI's "tier one" celebrities alone are reaching people, there are naturally going to be a large number of adolescents in that group. JLI Ex. 32, Chandler Dep. at 221:7-24; JLI Ex. 3, Chandler Rpt. at 37 (listing media reach of JUUL celebrities). Thus, the issue is not that JLI targeted only youth, it is that "they seemed quite comfortable with ... images that would appeal to youth in their influencer campaign." JLI Ex. 32, Chandler Dep. at 223:12-17; see also JLI Ex. 33, Cutler Dep. at 116:24-117:11 (noting the strong literature that youth are more susceptible and likely to try vaping).

¹⁰ JLI attacks several other experts on these same points. Plaintiffs are not responding point by point to every attack on every expert, as doing so would make this brief unbearably long, and it is also unnecessary given that JLI has organized its brief by topic, not by expert. The responses would be similar for every expert attacked for the same reason.

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There is ample quantitative analysis that supports the youth appeal of JUUL advertising. For instance, the chart posted above, *supra* section V.C.d, shows the strong relationship between JUUL sales and the youth vaping epidemic—i.e., when JUUL sales increased youth sales of e-cigarettes correspondingly increased. JLI Ex. 10, Halpern-Felsher Rpt. at 163. Other data shows a strong correlation between sales and the number of JUUL mentions on Twitter—a platform with 23% underage users. JLI Ex. 7, Emery Rpt. at 57; JLI Ex. 5, Drumwright Rpt. at 94; JLI Ex. 11, Jackler Rpt. at 137-62.

Daubert focuses on methodology, not on conclusions. Daubert, 509 U.S. at 595. Here, the experts used reliable methods to reach the opinions challenged in JLI's Section B. The experts' reports are filled with hundreds of citations to JLI's internal documents, the scientific literature and analysis by government bodies, and deposition testimony. See, e.g., JLI Ex. 10, Halpern-Felsher Rpt. at 39-49 (extensively citing scientific literature and JLI internal documents in addressing the importance of JUUL flavor pods); JLI Ex. 18, Prochaska Rpt. at 8-25 (extensively citing scientific literature in explaining the addictive properties of nicotine); JLI Ex. 5, Drumwright Rpt. at 90-105 (citing JLI documents and deposition testimony in explaining how JLI knew the risk that its marketing would appeal to adolescents and young adults). Their approach is at least as rigorous as the advertising analysis that this Court permitted in Post Foods. See Post Foods, 334 F.R.D. at 580.

There is also ample support for the experts' conclusion that JLI's marketing appealed to youth. As stated in the 2019 letter from several health organizations to the head of the FDA, "JUUL's products have been largely responsible for the extraordinary growth in youth e-cigarette use and the growth in the percentage of youth who have become addicted to e-cigarettes—an epidemic that continues to this day—with no measurable public health benefit." JLI Ex. 10, Halpern-Felsher Rpt. at 163; Ex. 11, Jackler Rept. 386, n. 262. With that context, it is difficult to imagine how an opinion that JLI's advertising appealed to youth could be excluded as unreliable.

All of JLI's attacks in Motion No. 1, Section B, raise issues for cross-examination, not grounds to exclude any expert.

c. <u>JLI's Arguments Against Experts Drumwright and Chandler Fail Because Marketing Claims do not Require Proof of Intent, and They are not Trying to Punish JLI for Adult Product use.</u>

JLI's next argument, in Section C of Motion #1 (pages 16-20), attacks the standards employed by two Plaintiffs' experts without identifying the legal standards that will govern the B.B. bellwether trial—or any other trial. To a large extent, these arguments have already been addressed in sections addressing preemption. *See* Section IV, *supra*.

JLI's argument against Drs. Drumwright and Chandler essentially ignore Rule 702 and

Daubert, but JLI appears to be arguing that their opinions do not "fit" the case. (See JLI Mot. 1 at 16.) The fit standard is a test of relevance. Daubert v. Merrell Dow Pharms., Inc., 43 F.3d 1311, 1321 n.17 (9th Cir. 1995). When assessing the relevance of expert testimony, it is important to consider the governing law. See Primiano v. Cook, 598 F.3d 558, 567 ("What is relevant depends on what must be proved, and that is controlled by Nevada law.").

JLI simply declares, with no citation to anything, that Plaintiffs' experts must conduct "a precise analysis of whether the advertising and marketing channels were selected to communicate with adult smokers or to specifically reach and resonate with youth." (JLI Mot 1. at 17). But JLI cites to no authority that subjective intent to harm a specific group is a requirement for each one of Plaintiffs' youth marketing claims. Under the California UCL, "plaintiff need not show that a UCL defendant intended to injure anyone." *Cortez v. Purolator Air Filtration Prod. Co.*, 23 Cal. 4th 163, 181 (2000). As another example, negligence claims universally require evidence of duty, breach of duty, and causation of damages. *See, e.g., McCall v. Wilder*, 913 S.W.2d 150, 153 (Tenn. 1995) (Tennessee law will govern the B.B. bellwether case). The touchstone of negligence of foreseeability of harm—not ill intent is required. *See Id*.

By ignoring the relevant legal standards, JLI's relevance argument itself fails the "fit" test. And even if intent to market to those under 18 years of age was an element of any of Plaintiffs' claims, Plaintiffs' experts' opinions concerning the youth-focused aspect of JUUL marketing would be relevant even if they did, themselves, prove intent. *See City of Tuscaloosa v. Harcros Chems.*, *Inc.*, 158 F.3d 548, 565 (11th Cir.1998) (testimony admissible if it helps the jury "to understand the evidence or to determine a fact in issue," and that it "must merely constitute one

piece of the puzzle that the plaintiffs endeavor to assemble before the jury"); *In re: Tylenol* (Acetaminophen), 2016 WL 807377, at *6 ("[W]hen an issue before the court pertains to the effect of a marketing an [sic] advertising campaign on a potential consumer, courts regularly permit expert testimony to aid the jury on the precise topic of marketing strategies."). JLI's failure to apply an appropriate standard dooms its arguments, and its specific attacks on experts Drumwright and Chandler also lack merit.

i) Dr. Drumwright

Dr. Drumwright's primary opinion as to JLI is that it "violated many professional norms, codes and standards." JLI Ex. 5, Drumwright Rpt. at 7-8.

JLI's first argument against her is pure semantics. Dr. Drumwright criticizes JLI for marketing to young adults, and JLI responds that marketing to young adults is not unlawful. (JLI Mot. 1 at 17-18). The issue, of course, is that marketing to young adults **and youth** is likely to result in underage users. *See* JLI Ex. 34, Drumwright Dep. at 69:20-70:4 (including young teens and "people whose brains are still developing" in the "youth and young adults" that JUUL's marketing strategies attracted). If JLI believes otherwise, it is free to cross-examine Dr. Drumwright on that point.

In opining that JLI violated the standards of numerous professional organizations, Dr. Drumwright is opining that JLI violated an industry standard of care. As the Ninth Circuit and a recent decision of this District have held, experts may opine about a company's violation of industry standards. *See Hangarter v. Provident Life & Acc. Ins. Co.*, 373 F.3d 998, 1016–17 (9th Cir. 2004); *United States v. Holmes*, No. 5:18-CR-00258-EJD-1, 2021 WL 2035177, at *4-5 (N.D. Cal. May 21, 2021). Perhaps JLI's most bizarre argument is that these standards are irrelevant because JLI has chosen not to join the cited organizations. (JLI Mot. 1 at 18). JLI's argument is akin to arguing that a doctor's decision not to join the American Medical Association absolves that doctor from a medical malpractice claim.

Ultimately, the critical standards are those set by law. For instance, one of Plaintiffs' claims in the B.B. bellwether case is for negligence. As noted above, in Tennessee negligence requires proof of a breach of duty. *McCall*, 913 S.W.2d at 153. More specifically, "[a]ll persons have a duty

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to use reasonable care to refrain from conduct that will foreseeably cause injury to others." *Id.* (citing *Bradshaw v. Daniel*, 890 S.W.2d 865, 870 (Tenn. 1993). The industry standards Dr. Drumwright cites help to define what conduct was "reasonable." Plus, it should hardly be controversial that marketing tobacco products to children is unreasonable.

JLI Ex. 10, Halpern-Felsher Rpt. at 13; *see also Id.* (quoting

JLI's final argument as to Dr. Drumwright is contradictory. It claims that she applied no

standard, one paragraph after listing out the numerous standards that she applied. (*See* JLI Mot. 1 at 18-19). In addition to the numerous professional standards that she considered, she also considered the standards set by the MSA and the Tobacco Control Act. JLI Ex. 34, Drumwright Dep. at 68:8-21. JLI's argument, therefore, has no merit.

ii) <u>Dr. Chandler</u>

Pltf. Ex. 3, PMTA Submission to FDA at 91.

JLI's arguments as to Dr. Chandler fare no better. JLI exaggerates one innocuous deposition answer. Asked whether digital marketing should be banned for age-gated products, Dr. Chandler stated that it should be done responsibly, and "I don't think it is what has happened here." He added that for age-gated digital products, close to 100% of the marketing should be to adults. JLI Ex. 32, Chandler Dep. at 190:22-191:24. He said that 100% "should be the standard," but he did not claim to be offering a legal standard.

Next, JLI claims that Dr. Chandler had no basis for concluding that JLI advertised in publications that skewed young, such as VICE. (JLI Mot. 1 at 19). Yet VICE, in which JLI advertised heavily, "bills itself as the #1 youth media magazine." JLI Ex. 3, Chandler Rpt. at 9 (emphasis added). This is also an area where Dr. Chandler's expertise is important. He is a marketing professor who previously worked for the largest digital marketing agency in the world.

Id. at 3. He is, therefore, capable of evaluating a publication or an advertising campaign and determining its target audience.

Finally, JLI asserts that Dr. Chandler is trying to punish JLI for marketing to adults, merely because he cannot identify the precise percentage of youth reached during the JUUL launch campaign. (JLI Mot. 1 at 20.) JLI ignores the concept of "bleed," which refers to advertising reaching audiences beyond the target. *See* JLI Ex. 3, Chandler Rpt. at 6-7 ("Because of the strategies JUUL deployed, considerable marketing bleed into youth markets was both inevitable and readily foreseeable."). JLI cites no law suggesting that it should be absolved for marketing children so long as it claims to have been targeting young adults. As discussed above, Plaintiffs have several claims, such as statutory claims and negligence claims, that do not require proof of intent.

Thus, JLI's arguments have no merit. At most, they are fodder for cross-examination, not exclusion.

d. <u>Plaintiffs' Experts Reliably Opine That Several of JUUL's</u> <u>Design Features Made the Product Attractive to Youth.</u>

JLI next stretches logic to its breaking point, insisting that because one of JLI's executives testified that they designed the product with adults in mind, Plaintiffs' experts cannot reliably opine that the device looked "cool" or that its design otherwise appealed to youth. (JLI Mot. 1 at 20-21.) Again, not all of Plaintiffs' claims depend on JLI's intent. *See* Section V.C.2, *supra*. Thus, JLI's assertion that "Plaintiffs must demonstrate that the appearance and design of the JUUL device were tailored and selected to appeal to youth," (JLI Mot. 1 at 20), is simply wrong, and that false premise undermines JLI's entire argument. Additionally, JLI fails to apply Rule 702 or *Daubert*. The closest JLI comes to explaining why anyone's opinion should be excluded is stating that "Plaintiffs' experts provide no reliable support" for "this opinion." (*Id.*). But it is unclear what "this opinion" means. JLI also criticizes these undefined experts for their lack of "empirical data," despite this Court previously holding that such data is not required. *Fujifilm*, 2015 WL 1737951, at *3; *see also* Section V.A., *supra* (studies not required).

As set forth above, several aspects of the JUUL design appealed to youth, including its hightech appearance that is easy to conceal; the use of flavors such as fruit, cool mint, and mango; and the smoother and less harsh hit from JUUL's nicotine salts. These opinions are supported by experts' analysis and observations, applying their considerable expertise in marketing; by scientific literature; and by JLI's documents and testimony. JLI's arguments for exclusion are without merit.

i) The "Cool" Appearance of the JUUL Device

JLI's first argument appears to be based on the logical fallacy that if JLI designed the product with adults in mind—which is unproven—then it could not have been appealing to youth. Clearly, both could be true. For instance, the flash-drive look of the product could achieve dual goals of not looking like a cigarette (for adults) and looking like a high-tech gadget (for youth). Again, JLI's intent in designing the device is irrelevant. JLI also fails to provide any basis to exclude the opinions of experts Grunberg, Eissenberg, and Noar, who are attacked in the first subsection. (See JLI Mot. 1 at 21-22.)

Dr. Grunberg's opinion is **not** that JUUL was "specifically designed for kids," but rather that "it is especially appealing to kids, youth, emerging adults." JLI Ex. 37, Grunberg Dep. at 73:3-12. He is not opining about JLI's intent, so his alleged failure to support an opinion about JLI's intent is immaterial to admissibility. *See Zeiger v. WellPet LLC*, 526 F. Supp. 3d 652, 671 (N.D. Cal. 2021) (countervailing evidence is irrelevant to admissibility unless it negates the reliability of the expert's opinion). Dr. Grunberg has extensively researched tobacco use, and he has learned that the "coolness" factor drives tobacco use among teens and pre-teens, but not among adults. JLI Ex. 37, Grunberg Dep. at 76:16-77:1-10.

Id. at 72:6-25. Documents show that JLI knew that its device was appealing to youth. See JLI Ex. 8, Grunberg Rpt. at 106. For instance, he cited a 2018 study concluding that the device was "HUGELY popular" among teens due to its sleek design. Id. at 108. Dr. Grunberg also cited studies showing that social acceptability and product aesthetics have driven JUUL use among youth and young adults. Id. at 118 & n.295.

JLI's arguments as to Drs. Eissenberg and Noar fare no better. JLI claims that their opinions about the attractiveness of JUUL's design could also apply to young adults or to other ENDS products. (JLI Mot. 1 at 21-22.) Missing from these arguments is any analysis as to why those points would render the experts' opinions about **JUUL's** attractiveness to **youth** unreliable. JLI's

additional arguments border on the absurd. For instance, JLI claims that Drs. Eissenberg and Levy disagree about the extent of the vapor cloud from JUUL. (*See id.*). Their opinions—that the vapor cloud dissipates quickly and can be played with—are not mutually exclusive, but even if they were, disagreements among experts are not a basis to exclude anyone's opinion. *See Scripps Health*, 2021 WL 3372835, at *7. Further, the attack that a study relied on by Dr. Noar refers to "pod mod devices like JUUL," as opposed to JUUL exclusively, is meaningless. The study clearly references JUUL. (JLI Mot. 1 at 22.) All of these issues are for cross-examination, not exclusion.

ii) JUUL Design's Appeal to Youth

Every expert's opinion that JUUL's design appeals to youth is reliable. As explained above, when experts offer opinions in social sciences, the reliability of those opinions rests on the qualifications of the experts and the application of their experience and expertise to the facts. *See Golden W. Trading, Inc. v. BelGioioso Cheese, Inc.*, No. CV097803GHKAGRX, 2012 WL 12953447, at *1 (C.D. Cal. Apr. 16, 2012) (quoting *United States v. Simmons*, 470 F.3d 1115, 1123 (5th Cir. 2006)); *Tylenol*, 2016 WL 807377, at *5, citation omitted ("A marketing professional's review and analysis of company documents to extrapolate marketing strategies, coupled with the expert's experience and background may be enough to establish that the expert's methodology is reliable").

Plaintiffs' experts are all well-qualified and extremely knowledgeable about issues related to marketing and youth nicotine use. *See* Section II, *supra*. They are not speculating, as JLI alleges (JLI Mot. 1 at 22), in opining that the JUUL design appealed to youth. The attacked experts, Drs. Eissenberg, Grunberg, Jackler, Levy, Shihadeh, Prochaska, and Winickoff, all reviewed and analyzed the data, applied their expertise and experience, and determined that JUUL's "cool" design appealed to youth. JLI Ex. 6, Eissenberg Rpt. at 131-33; JLI Ex. 8, Grunberg Rpt. at 107-09; JLI Ex. 37, Grunberg Dep. at 38:3-44:22, 107:11-15; JLI Ex. 11, Jackler Rpt. at 287-92; JLI Ex. 13, Levy Rpt. at 33-38; JLI Ex. 23, Shihadeh Rpt. at 53-54; JLI Ex. 18, Prochaska Rpt. at 36-38; JLI Ex. 47, Prochaska Dep. at 264:15-265:15; JLI Ex. 25, Winickoff Rpt. at 184-87.

JLI again criticizes the experts for failing to conduct empirical studies, even though such studies are unnecessary. *See* Section V.A., *supra*. Moreover, some experts did rely on studies. For

instance, Dr. Winickoff relied on Ramamurthi et al., 2018, for the conclusion that JUUL's design is cool, small, and sleek; looks like a high-tech USB product and not a cigarette; and is concealable with low aerosol output and no strong scent—all of which appeals to youth. JLI Ex. 25, Winickoff Rpt. at 184. Dr. Grunberg conducted an empirical analysis of which factors contributed to the rise in underage use of ENDS products in 2018. JLI Ex. 37, Grunberg Dep. at 102:15-103:7.

JLI Ex. 8, Grunberg Rpt. at 107-08. Showing its inconsistency, JLI attacks Dr. Grunberg's reliance on a study of adults, immediately after criticizing him for doing "no research on adult smokers." (JLI Mot. 1 at 22.) Other experts chose to rely on real-world data. *See*, *e.g.*, JLI Ex. 34, Drumwright Dep. at 185:11-14 ("[T]here are many indicators of JUUL's sales to youth in the data I had, so didn't need to do that kind of empirical work myself."). Still others noted the difficulty of conducting reliable empirical studies. *See*, *e.g.*, JLI Ex. 37, Grunberg Dep. at 103:8-20. To the extent that Plaintiffs' experts did not rely on certain data, that issue goes to weight of an expert's opinions, not their admissibility. *See City of Pomona v. SQM N. Am. Corp.*, 750 F.3d 1036, 1044 (9th Cir. 2014) (stating that "[t]he district court is not tasked with deciding whether the expert is right or wrong, just whether his testimony has substance such that it would be helpful to a jury").

JLI's additional arguments are irrelevant or illogical. JLI attacked Dr. Grunberg's opinion that JUUL's design appealed to youth by referencing data from the National Institute on Drug Abuse's "Monitoring the Future" survey. JLI Ex. 37, Grunberg Dep. at 79:18-82:1. The survey outlined the top ten factors that influenced youth to use ENDS products, and looking "cool" ranked seventh. *Id.* As Dr. Grunberg explained, even if looking "cool" did not top the list, "these are still reasons that are cited and that are influential." *Id.* at 80:15-21. "Coolness" also may have factored into other reasons, just not by that word. *Id.* at 81:20-82:1.

JLI also illogically argues that JUUL's design needed to be unique in the market for it to appeal to youth. JLI attacks experts Jackler, Levy, and Winickoff for opining that JUUL "uniquely" appealed to youth. JLI seems to argue that JUUL's design could not appeal to youth because other devices had similar features. This defies logic. First, other vaping devices are not at issue here.

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Second, a device's design does not need to be unique in the market to uniquely appeal to youth. As Dr. Jackler notes, "JUUL-a-likes" were not common until after JUUL's rise. JLI Ex. 40, Jackler Dep. at 185:15-186:8. Third, some of JUUL's features were unique and increased youth appeal. While other devices could be concealed in a pocket or up a sleeve, JUUL could hide in plain sight because it looked like tech or a USB device. *Id.* at 171:2-9 ("JUUL really broke the ground there on stealthiness in the sense that it could hide in plain sight."). Dr. Levy opines that several design factors made JUUL "uniquely and particularly attractive to youth," such that JUUL "caused the youth vaping epidemic." JLI Ex. 13, Levy Rpt. at 33-38. JUUL had "party mode"—lights flashing in various colors, activated by puffing on the JUUL—that were particularly attractive to youth. *Id.* at 36-37; *see also* JLI Ex. 25, Winickoff Rpt. at 185-86; JLI Ex. 18, Prochaska Rpt. at 36-38.

Finally, Plaintiffs' experts did not need to evaluate adult appeal to opine on youth appeal. JLI attacks Drs. Eissenberg and Grunberg because they did not consider JUUL's appeal to adults when they concluded that JUUL appealed to youth. JLI's arguments continue to be inconsistent and illogical. Previously, JLI criticized experts because they included opinions about young adults. *See* Section C.2.b., *supra*. JLI's argument against Dr. Eissenberg is entirely unsupported, and JLI cherry-picks only a sliver of Dr. Grunberg's deposition. (See JLI Mot. 1 at 22-23.) Regardless, Drs. Grunberg and Eissenberg assert that JUUL's design appealed to youth, which is the critical issue, and those opinions are supported by the record. *See*, *e.g.*, JLI Ex. 37, Grunberg Dep. at 76:16-77:10 (stating that his opinions are "not just based on my personal experience, but research I've done with thousands of smokers over the years, that description ["cool"] has been focused on preteens, teens, and it pretty well disappears by the time they're in their early 20s"); JLI Ex. 6,

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¹¹ JUUL's design also was "skinz" friendly. JLI Ex. 13, Levy Rpt. at 37. "Skinz" are stick-on covers used to personalize JUUL devices. They were made possible by JUUL's sleek, tech-like design, and the ability to add them made JUUL particularly attractive to youth. *Id.* at 34, 37. JLI's reliance on *Colgate v. JUUL Labs, Inc.*, 402 F. Supp. 3d 728, 760 (N.D. Cal. 2019), in claiming that it cannot be liable for skinz is misplaced. Plaintiffs are not contending that JLI is vicariously liable for a third party's conduct. Rather, JLI is directly liable for its youth-appealing design, which accommodated "skinz." In *Colgate*, this Court held only that JLI was not vicariously liable under a ratification theory because the plaintiff did not allege that third-party "@JUULnation" was JLI's agent. *Id.* Plaintiffs are not alleging vicarious liability based on the actions of the "skinz" manufacturer, so *Colgate* is irrelevant.

Eissenberg Rpt. at 132 ("JLI gave JUUL a sleek and 'cool' design aesthetic that appealed to young and nicotine naïve individuals.").

iii) Alternative Designs

Finally, this Court should reject JLI's argument that it was impossible to make changes to the device after the FDA's deeming rule took effect. Notably, JLI has provided no evidence that it attempted to apply for changes to the product after the deeming rule went into effect and such attempt was rejected, so it cannot establish that it is impossible to make such changes. Courts have rejected similar arguments in the context of drugs and medical devices, where companies have alleged they could not have added safety features without FDA approval. *See, e.g., Wyeth v. Levine*, 555 U.S. 555, 571–73 (2009); *Kaiser v. Johnson & Johnson*, 947 F.3d 996, 1009–10 (7th Cir. 2020). Thus, JLI has failed to establish that it was unable to add safety features to JUUL after the deeming rule went into effect.

JLI also fails to establish that proposed changes before that time were unfeasible. While JLI mentions several experts in passing, its argument about the feasibility of design changes before 2016 attacks only one expert, Dr. Grunberg. (See JLI Mot. 1 at 25-26.) Dr. Grunberg opines that several safer alternative designs were available to JLI. JLI Ex. 8, Grunberg Rpt. at 125-27. JLI challenges the feasibility of the proposed alternatives, but as to his first three proposals there is no legitimate debate. JLI clearly could have used a lower concentration of nicotine in its formula, could have marketed only tobacco flavors, and could have designed the device in a way to make it look less high-tech and more like a cigarette. Id. at 125-26. Only his final suggestion is challenged as not being feasible:

as not being feasible:

Id. at 127.

. JLI Ex. 18, Prochaska Rpt. at

Thus, there is evidence to support Dr. Grunberg's contentions, and JLI's argument is a basis for cross-examination, not exclusion. *See In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 744 (3d Cir. 1994) ("A judge will often think that an expert has good grounds to hold the opinion that he or she does even though the judge thinks that the opinion is incorrect.").

3. Dr. Proctor's Opinions Should Not be Excluded

Despite Dr. Proctor's unparalleled credentials and experience, JLI asks this Court to "exclude Proctor from testifying altogether" because, it asserts, his opinions are irrelevant, and some courts have curtailed the scope of his past testimony. (*See* JLI Mot. 1 at 26.) In support of this argument, JLI has scoured Dr. Proctor's decades-long record and cherry-picked a handful of occasions in which courts have limited his testimony to fit the facts of the trial.¹² (*See* JLI Mot. 1 at 28.)

At trial, Dr. Proctor will not testify as to whether JLI's advertising appealed to Plaintiff specifically, but will draw comparisons between JLI's marketing and past tobacco marketing to identify strategies, codes, and themes that have been conclusively established as appealing to youth by the industry's own research and court orders. *See United States v. Philip Morris USA, Inc.*, 449 F. Supp. 2d 1, 616–639 (D.D.C. 2006) ("Defendants' Marketing Employs Themes Which Resonate With Youth"). His testimony will equip the jury with the interpretation tools required to assess such content within historical context of what JLI was on notice of when launching a tobacco

¹² JLI cites one court's order of a mistrial after a comment by Dr. Proctor potentially prejudiced the jury by repeating a word contained in industry documents, and another's statement that Dr. Proctor would not testify live in its courtroom again. (*See* JLI Mot. 1 at 28; JLI Mot. 4 at 5.) These events took place in 2008 and 2010, respectively, and are not representative of Dr. Proctor's demeanor on the stand. Indeed, courts have permitted Dr. Proctor to testify in dozens of trials since with no such issues. *See* Pltf. Ex. 5, Proctor App'x I at 18–19. JLI's reference to two errors in Dr. Proctor's long and esteemed record is needlessly inflammatory. Plaintiffs' counsel are mindful of the rules, have every interest in ensuring a smooth trial, and will instruct all expert witnesses appropriately.

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See Pltf. Ex. 1. Asseilv Dep. at 108:1-
Pltf. Ex. 2. Dunlan Dep. at 117:18-24
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product. See JLI Ex. 20, Proctor Rpt. at 88 ("Cigarette makers have long recognized the power of images, observing in their private communications that most people don't actually 'read' a magazine, they look at the pictures. Marketing is all about harnessing the power of suggestive images, and by exploring the rich body of marketing theory and practice in the archives one can learn what kind of tools are being used to target different kinds of people."). Applying his extensive study of these types of marketing techniques, Dr. Proctor's opinions will assist the jury in assessing whether JLI's marketing appealed to youth. His testimony does not, as JLI suggests, "conflate" JUUL with combustible cigarettes; it discusses the similarities in marketing strategies. The jury is well-equipped to tell the difference without being unduly confused.

JLI does not cite any determination by any court that Dr. Proctor is unqualified, or that his testimony would be unhelpful to a finder of fact. Cf. United States v. Newmont USA Ltd., No. CV-05-020-JLQ, 2007 WL 4856859, at *2 (E.D. Wash. Nov. 16, 2007) ("Only if the expert's opinion is so fundamentally unsupported that it can offer no assistance to the finder of fact is exclusion justified under Fed.R.Evid. 702."). Even on the rare occasions where courts have limited the scope of Dr. Proctor's testimony, they have recognized his expertise and allowed him to give critical historical context to the jury. See, e.g., Delancy v. R.J. Reynolds Tobacco Co., No. 432008CA67, 2018 WL 11341743, at *5 (Fla. Cir. Ct. Sep. 12, 2018) (allowing Dr. Proctor to "place company documents in historical context"); In re: Engle Progeny Cases Tobacco Litigation, No. 2008-CV-022558 (19), 2017 WL 8728335, at *1 (Fla. Cir. Ct. Apr. 17, 2017) (allowing Dr. Proctor to testify "regarding tobacco industry documents and historical records to cigarette design, casual inference, and epidemiological studies"); In re: Engle Progeny Cases Tobacco Litigation, No. 07-036745 (08), 2019 WL 13043170, at *2 (Fla. Cir. Ct. Feb. 22, 2019) (allowing Dr. Proctor to testify "from an historical perspective about cigarette design and the chemical composition of cigarettes"); Hubbird v. R. J. Reynolds Tobacco Co., No. 2012CA018904, 2014 WL 5795298, at *2 (Fla. Cir. Ct. Aug. 11, 2014) (allowing Dr. Proctor to give "opinions on history of knowledge and design"). That courts have excluded certain opinions by Dr. Proctor in other cases is irrelevant to whether the Court should admit entirely different opinions from Dr. Proctor in this case.

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Dr. Proctor's testimony will be appropriately limited to his expertise as a tobacco historian, which courts have concluded is helpful to the finder of fact. See Schwab v. Philip Morris USA, Inc., 449 F. Supp. 2d 992, 1209 (E.D.N.Y. 2006), rev'd on other grounds by McLaughlin v. Am. Tobacco Co., 522 F.3d 215 (2d Cir. 2008) ("[Dr. Proctor's] testimony is useful as historical background to show the development of a scientific consensus and its gradual infusion into the general knowledge base of scientists and laypersons. This historical overview will be helpful to the jury in organizing in its mind a huge flow of documentary and other evidence over many years."). To the extent JLI attacks references to the practice in the cigarette industry of destroying documents or Pritzker's prior roles in marketing conspiracies (JLI Mot. 1 at 27), Dr. Proctor agrees not make such statements at trial. 14 Nor will he offer an opinion that JLI was a party to the MSA and bound by its terms for that reason, (see JLI Roadmap at 17; JLI Mot. 1 at 52-53), or legal conclusions as to whether JUUL products are defective, (see Id. at 34).

D. Plaintiffs' Experts Provide Reliable Opinions Regarding the Connection **Between JUUL Marketing and Underage Use**

Numerous experts conduct a robust analysis connecting JUUL's marketing to the dramatic rise in JUUL use by underage persons that coincided with the rise of JUUL itself. JLI again primarily focuses on what Plaintiffs' experts have allegedly not done. But there is no bright-line rule that opinions cannot be relevant to causation and reliable absent formal studies. Here, Plaintiffs' experts provide reliable opinions concerning causation and youth marketing rooted in their experience and review of the record. JLI's argument are legally irrelevant and, at most, fodder for cross examination at trial.

¹⁴ Dr. Proctor expressly recognizes that "Juul and the other e-cigarette manufacturers were unconstrained by any of the limits faced by traditional cigarette makers when it came to marketing ... because they had not signed onto the MSA." JLI Ex. 20, Proctor Rpt. at 41. But Dr. Proctor can and will speak to the MSA as setting standards of care for tobacco manufacturers, as Altria has stated it does. See Pltf. Ex. 6, Willard Dep. Ex. 4, at 8152 ("We believe that going over and above what's required by the MSA is an essential component of being a responsible marketer of tobacco products.").

1. The Relevant Standards for Causation

JLI seeks to exclude Plaintiffs' experts' opinions (again without specifying which opinions from which experts) because the experts' opinions purportedly fail to satisfy Plaintiffs' "burden of proving causation." (JLI Mot. 1 at 29). This argument is flawed as a matter of law, rendering the vast majority of JLI's arguments inapposite.

First, whether Plaintiffs have sufficient evidence to carry their burden at trial is, at most, a summary judgment argument, not a *Daubert* issue. "[N]either Rule 702 nor *Daubert* requires that an expert's testimony, in part or in whole, singlehandedly prove an element of the offering party's case for it to be admissible." *In re High-Tech Employees Antitrust Litig.*, 2014 WL 1351040, at *24 (N.D. Cal. Apr. 4, 2014) (citation omitted). As the D.C. Circuit explained, "evidence does not warrant exclusion simply because it fails to establish the causal link to a specified degree of probability. The fitness prong of the *Daubert* admissibility inquiry primarily concerns relevance. The dispositive question is ... not whether the testimony satisfies the plaintiff's burden on the ultimate issue at trial." *Ambrosini v. Labarraque*, 101 F.3d 129, 135-36 (D.C. Cir. 1996). In other words, even where an expert opinion does not "constitute proof" of a claim or element, it "should [be] admitted for whatever probative value it [has]." *Obrey v. Johnson*, 400 F.3d 691, 697 (9th Cir. 2005); *see also* Fed. R. Evid. 402 ("relevant evidence is admissible"). With respect to causation, an expert need not "say with certainty" that causation was established, as "a jury could reasonably infer causation from [the expert's] report and other evidence." *Pyramid Techs., Inc. v. Hartford Cas. Ins. Co.*, 752 F.3d 807, 816 (9th Cir. 2014).

Second, even if the standard of proof at trial for causation was relevant to a *Daubert* analysis, JLI makes no effort to evaluate the actual legal claims at issue and their related causation standards. With respect to B.B.'s claims, under Tennessee law the challenged conduct need only be a "substantial factor." *See King v. Anderson Cnty.*, 419 S.W.3d 232, 247 (Tenn. 2013); *Pellicano v. Metro. Gov't of Nashville & Davidson Cnty.*, No. 03-292, 2004 WL 343951, at *3 (Tenn. App. Feb. 23, 2004) (discussing causation in the context of multiple causes). The "substantial factor" test also applies to plaintiffs' RICO claims, *OKI Semiconductor Co. v. Wells Fargo Bank, Nat. Ass'n*, 298 F.3d 768, 773 (9th Cir. 2002), and the government entity nuisance

claims, *People v. ConAgra Grocery Prods. Co.*, 227 Cal. Rptr. 3d 499, 543 (Cal. Ct. App. 2017). Thus, at the *Daubert* stage, an expert's opinion need only be relevant to whether the conduct was a substantial factor in the alleged harm. *See Messick v. Novartis Pharmaceuticals Corp.*, 747 F.3d 1193, 1197 (9th Cir. 2014) (under the substantial factor test, testimony was admissible if it showed that an injury is related to product use, even if it did not demonstrate that the product use caused the injury). And under the class's UCL claim concerning youth marketing, "only the named plaintiff ... need demonstrate injury and causation." *Plascencia v. Lending 1st Mortg.*, 259 F.R.D. 437, 448 (N.D. Cal. 2009). The "may have been acquired" standard under the UCL "focuses on the defendant's conduct and is substantially less stringent than a reliance or 'but for' causation test." *Sevidal v. Target Corp.*, 189 Cal. App. 4th 905, 924 (Cal. Ct. App. 2010).

Expert Opinions Can be Relevant to Causation Even if They Are Not Based on Formal Studies or Regressions

Most of JLI's arguments are repackaged versions of the same assertion: that Plaintiffs' experts' opinions are not admissible unless they are based on formal consumer studies, and that no such studies exist. (JLI Mot. 1 at 29-33.) As noted above, studies are not a prerequisite to admissibility with respect to marketing issues. *See* Section V.A., *supra*. The only case JLI cites has nothing to do with marketing or social science; it concerned medical opinions concerning the safety of dietary supplements. *Metabolife Int'l, Inc. v. Wornick*, 264 F.3d 832, 840-42 (9th Cir. 2001). JLI provides no support for the conclusion that any expert analysis lacking a formal study or regression is inadmissible *ipse dixit*. And, as noted above, Plaintiffs' experts have relied on empirical research that JLI's motion chooses to ignore and explained why they did not conduct studies in other circumstances. *See* Section V.C.2., *supra*.

3. Plaintiffs' Expert Opinions Concerning Causation Are Reliable

JLI challenges Plaintiffs' experts' opinions concerning the causal link between JUUL marketing and youth usage on a variety of other grounds. But none of these are a relevant determination of admissibility under *Daubert*.

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a. The Court Should Reject JLI's Efforts to Exclude Entire Opinions Because of Specific Word Choice

JLI takes issues with Plaintiffs' experts isolated use of "obvious" and other similar words in their depositions to describe the causal relationship between JUUL marketing and underage use. (JLI Mot. 1 at 33.) Aside from using certain words and phrases, JLI's argument fails to identify any specific opinions or analyses it seeks to exclude. Further, while JLI presents these cherry-picked statements as being unsupported, it fails to engage with the substance of the expert reports or the analyses that formed the basis of those opinions (which are discussed above). Unsurprisingly, JLI cites no cases in which an expert's characterization of his or her conclusions as "obvious" in a deposition would support the exclusion of that expert's entire opinions.

JLI points, for example, to statements in Dr. Proctor's deposition that he believed the causal relationship between JUUL marketing and youth vaping was "obvious" and "pretty clear" as an apparent basis to exclude the entirety of his youth marketing opinions. (JLI Mot. 1 at 33-34.) These statements are not improper ipse dixit; they are conclusions drawn from Dr. Proctor's decades of experience studying tobacco marketing. In his historical scholarship, Dr. Proctor has lectured, published, testified, and taught extensively on the history of cigarette marketing and has reviewed countless tobacco advertisements—there are 56,000 alone in the SRITA archive that he co-created. See JLI Ex. 20, Proctor Rpt. at 2-3, 88–89; JLI Ex. 49 Proctor Dep. at 25:2 ("I do a lot of research in marketing."); see also Pooshs v. Phillip Morris USA, Inc., 287 F.R.D. 543, 553 (N.D. Cal. 2012) (finding that despite epidemiologist not having a marketing degree, he was qualified by education, experience, and training to opine regarding advertising and marketing in the area of public health). As in several past tobacco trials, Dr. Proctor is qualified to speak to marketing issues, and he can draw on his experience with industry documents to identify historical themes and tactics that cigarette companies knew appealed to youth. See JLI Ex. 20, Proctor Rpt. at 41–46 (discussing the history of cigarette marketing tactics and drawing comparisons to JLI's). To the extent Dr. Proctor uses the word "obvious" at trial, JLI is welcome to cross-examine him on that word choice. The same is true with statements by any of Plaintiffs' other experts.

JLI next mischaracterizes certain opinions to try to create the false impression that Plaintiffs' experts have conceded causation. For instance, JLI argues that statements acknowledging the difficulty of measuring causation empirically in the marketing context means that Plaintiffs have "fail[ed] to meet their burden" because they cannot "prove causation." (JLI Mot. 1 at 34.) As noted above, this argument is both irrelevant to *Daubert* and the youth marketing claims, and it misstates the standards for causation, even at trial. Simply put: JLI's argument has no place in a *Daubert* motion.

The statements JLI highlights from Drs. Jackler, Cutler, and Halpern-Felsher support the common-sense proposition that when dealing with issues of social science, causation cannot be determined in the same way it can be, for example, when dealing with matters of chemistry. They underscore the reality that "the research, theories and opinions cannot have the exactness of hard science methodologies." *Golden W. Trading*, 2012 WL 12953447, at *1. Several of Plaintiffs' experts have explained that in the context of social science research and certain issues presented in this litigation, the type of empirical studies JLI demands are simply not practical, nor are they a necessary part of reliable social science analysis. *See* JLI Ex. 56, Woolley Dep. at 368:14-21 ("There are some methods of qualitative social science that do replication. Field research methods done ... in this context would not be replicable. And ... social scientists in this context would expect that."); JLI Ex. 54, Winickoff Dep. at 100:4-13 (explaining that certain qualitative research and meta-analyses do not fall into the category of being "objective and repeatable")).

JLI nonetheless seeks to spin these statements into a concession that it is impossible for Plaintiffs to prove causation. But JLI's argument rests on the mistaken proposition that "proving" causation requires a specific type of evidence—*i.e.*, opinions based on particular types of studies. As noted above, this is incorrect. *See* Sections V.A and V.C.2.a, *supra*. None of Plaintiffs' experts stated that it was impossible to offer a reliable opinion concerning the causal link between JUUL marketing and youth usage. Instead, some acknowledged that there were challenges to drawing that connection *in particular ways*. JLI makes no effort to explain how the statements it highlights

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render the analysis and opinions the experts *do* offer unreliable or irrelevant to the determinations the jury will be asked to make concerning causation.

None of the cases JLI cites support the exclusion of any portion of the opinions of Drs. Jackler, Cutler, and Halpern-Felsher. In Liaw v. United Airlines, Inc., 2019 WL 6251204 (N.D. Cal. Nov. 22, 2019), the expert opined that a normal flight landing caused a bulging disk in the plaintiff's back. Id. at *4. Unlike here, the expert offered no analysis that would even suggest that one event made the other more likely. Id. Here, Drs. Jackler, Cutler, and Halpern-Felsher extensively discuss how JUUL marketing would have been, and was, appealing to youth and how that appeal led to increases in JUUL usage by youth. JLI Ex. 11, Jackler Rpt. at 381-99 (discussing how JUUL marketing contributed to the youth vaping epidemic); JLI Ex. 10, Halpern-Felsher at 161-220; JLI Ex. 4, Cutler Rpt., ¶¶ 144-61 (discussing the relationship between JUUL youth use and sales) (emphasis in original), ¶¶ 162-72 (discussing product features associated with youth substance abuse). This is much more than the "bare bones" correlation suggested by the expert in Liaw. In In re TMI Litigation, 193 F.3d 613 (3d Cir. 1999), relied on by JLI, the issue was the plume dispersion of chemicals, for which there is a well-defined set "standard and generally accepted computer models" and used a model that had never been used in the relevant community. *Id.* at 668. Here, the selection of a computer model is not at issue, and Drs. Jackler, Cutler, and Halpern-Felsher used accepted methods of social science research and analysis to reach their opinions.

Lastly, to the extent that JLI believes its experts—including Dr. Rossi—conducted a better analysis than Plaintiffs' experts, that is a matter of the relative weight of the opinions, and not an issue of admissibility. JLI cites no cases holding otherwise.

c. <u>A Primary Role of Experts is to Synthesize Evidence and Draw Conclusions</u>

JLI next challenges the testimony of experts Drs. Emery, Levy, Winickoff, and Noar for what it characterizes to be "subjective syntheses of anecdotal evidence, reflections on one-off studies, or summaries of company documents." For example, JLI criticizes Dr. Levy for noting her clinical experience with patients who use Juul. (JLI Mot. 1 at 36.) But Dr. Levy does not rely solely on anecdotal data; she uses her clinical experience mainly to confirm the results of other studies.

See, e.g., JLI Ex. 13, Levy Rpt. at 12 (discussing the National Cancer Institute's Monograph regarding the relationship between tobacco advertising and promotion and increased tobacco use, as well as recent studies showing that youth perceived vaping advertisements to be for them); id. at 33 (noting that the results of a nationally representative survey in which "80% of youth said that they use e-cigarettes because they believe they are less harmful than cigarettes" were "commensurate with my clinical experience"). "An expert may base an opinion on facts or data in the case that the expert has been made aware of or personally observed." Fed. R. Evid. 703. Dr. Levy's testimony is very different from the expert reports excluded in drug product or toxic tort cases such as Casey v. Ohio Med. Prod., 877 F. Supp. 1380, 1385 (N.D. Cal. 1995), McClain v. Metabolife Int'l, Inc., 401 F.3d 1233, 1254 (11th Cir. 2005), or Soldo v. Sandoz Pharms. Corp., 244 F. Supp. 2d 434, 542 (W.D. Pa. 2003), where the courts held that observational case reports were insufficient to show that a substance could cause the plaintiffs' injuries in the absence of any epidemiological studies or other studies of the danger of the product.

JLI also cites no authority for its suggestion that there is something improper about an expert summarizing the relevant research, evaluating the factual record, or including among the sources considered a study whose conclusion does not conform exactly with the expert's ultimate opinion. This is because an expert's role is precisely to evaluate the facts of the case (even the facts that may be contrary to the expert's opinion) in light of the prevailing scientific literature and the expert's own experience in his or her field of expertise. *See, e.g., Sumotext Corp. v. Zoove, Inc.*, No. 20-17245, 2021 WL 4988024, at *2 (9th Cir. Oct. 27, 2021) (affirming district court's admission of expert testimony "based on, inter alia, her experience as an economist, her review of customer data and financial data provided by the parties, independent industry research, and her review of deposition testimony"); *In re Roundup Prod. Liab. Litig.*, 390 F. Supp. 3d 1102, 1139 (N.D. Cal. 2018) (finding expert's testimony admissible where expert conducted "literature search to identify the relevant epidemiology evidence, assessed the quality of each pertinent study, and used her judgment to determine how the results of these studies fit together"); *United States v. W.R. Grace*, 504 F.3d 745, 765 (9th Cir. 2007) (noting that whether an expert's opinion testimony satisfies Rule 702 "requires consideration of the overall sufficiency of the underlying facts and data" and

explaining that the district court erred in "conduct[ing] a document-by-document Rule 702 analysis that deconstructed the experts' testimony in a manner not contemplated by Rule 702"). The Court should reject JLI's attempt to disguise what is ultimately a critique going to the weight of Plaintiffs' expert testimony as a concern over the experts' methodologies.

d. <u>Dr. Cutler's Opinions Are Reliable and Based on Well-</u> Established Economic and Econometric Methodologies

Dr. Cutler—one of the nation's leading health economists who regularly examines causal relationships between addictive goods and subsequent harms, as described in more detail above—offers several key opinions from an economic perspective regarding JLI and Altria, including that their actions increased youth vaping rates. *See* JLI Ex. 4, Cutler Rpt. at ¶ 8. Dr. Cutler also opines that (1) a large share of JUUL use can be attributed to youth usage, (2) there is no evidence, as JLI contends, that e-cigarette use is a substitution for combustible cigarette use, (3) short-term misconduct can lead to long-term harms, (4) a youth vaping epidemic exists, and (5) there are substantial costs imposed on counties, cities, and schools as a result of the youth vaping epidemic. *Id.* JLI does not challenge any of these latter opinions. Instead, though it is not entirely clear which portions of Dr. Cutler's report JLI seeks to strike, JLI contends that Dr. Cutler's "but-for" analysis is "incomplete ... unreliable and inconsistent with the relevant data." (JLI Mot 1 at 38.) In other sections of its brief, JLI also sprinkles a potpourri of hard-to-follow arguments referencing Dr. Cutler's analyses.

But all of JLI's arguments fall woefully short of the *Daubert* standard justifying exclusion. As an initial matter, JLI only identifies a portion of Dr. Cutler's causation analysis as allegedly problematic. In other words, the specific but-for analyses JLI challenges are just *one aspect* of Dr. Cutler's overall but-for analyses regarding JLI. *See, e.g.*, JLI Ex. 4, Cutler Rpt. at ¶¶ 144-61 (describing various analyses to guide the but-for inquiry, including (1) that "the vast bulk of vaping increases after 2016 were sales of JUUL" and (2) utilizing "data from the longitudinal PATH study" to conclude that "JUUL turned youth *experimentation* with vaping into *regular youth use* of vaping products") (emphasis in original). JLI also ignores that Dr. Cutler identifies key features of JUUL products and marketing that are associated with youth substance abuse. In particular, Dr. Cutler

draws upon peer-reviewed literature, discovery from this case, and JUUL sales to establish that youth were particularly susceptible to JUUL advertising and that JUUL's flavors appealed toward youth. *Id.* at ¶¶ 162-72. These analyses, which JLI does not challenge, further support and confirm Dr. Cutler's conclusion that JUUL is responsible for increasing youth vaping rates.

Concerning the portion of Dr. Cutler's but-for analyses that JLI does challenge, JLI comes nowhere near establishing that they are scientifically improper or the result of an unreliable methodology. For instance, Dr. Cutler utilizes two different regression analyses to estimate the but-for rate of youth vaping in the absence of JUUL. Dr. Cutler's first regression analysis, he "uses data on youth demographics and behaviors with respect to other risky activities and substances to predict likely vaping rates." JLI Ex. 4, Cutler Rpt. at ¶ 154. Dr. Cutler specifically included a wide variety of different independent variables in his regression analysis to show how changes in demographics would have affected youth vaping. *Id.* at ¶¶ 155-158, App'x 9. Dr. Cutler's second regression analysis estimates youth demand for e-cigarettes as a function of youth characteristics, state-level tobacco policies, and measures of the prices of cigarettes and e-cigarettes. *Id.* at ¶ 159. This regression similarly employs a comprehensive set of independent variables that may impact the probability of vaping. *Id.* at ¶¶ 160-161, App'x 10. Collectively, these regressions utilize more than 80 different variables resulting in approximately half a million observations.

JLI nevertheless claims Dr. Cutler did not apply standard econometric techniques (JLI Mot. 1 at 40). But the utilization of regressions is one of the most ubiquitous econometric methodologies used by economists and statisticians. And to the extent, JLI argues that Dr. Cutler's results are unreliable because he did not apply the correct variables (JLI Mot. 1 at 39), this standard refrain at the *Daubert* stage can be easily rejected. JLI essentially argues that Dr. Cutler's analysis suffers from omitted variable bias, but the Supreme Court recognizes that the failure to include variables in a regression model generally affects the model's weight, rather than its admissibility. *Bazemore v. Friday*, 478 U.S. 385, 400 (1986) (Brennan, J., concurring in part, joined by all Justices). Thus, a party cannot exclude a regression analysis simply by pointing to variables not taken into account. *Mehus v. Emporia State Univ.*, 222 F.R.D. 455, 462 (D. Kan. 2004); *Maitland v. Univ. of Minnesota*, 155 F.3d 1013, 1017 (8th Cir. 1998) ("[I]f a regression analysis omits variables,

it is for the finder of fact to consider the variables that have been left out of an analysis and the reasons given for the omissions, and then to determine the weight to accord the study's results.").

In trying to demonstrate that Dr. Cutler relied on the wrong variables, JLI relies on the sweeping conclusions reached by one of its own economic experts—one of four they retained to challenge Dr. Cutler. ¹⁵ (JLI Mot. 1 at 38-39 (citing to portions of the Orszag report)). JLI specifically claims Mr. Orszag, who notably does not possess a Ph.D in economics, used "survey data"—without identifying which survey data he specifically applied—that yields different results than Dr. Cutler. *Id.* Even if the Court were to accept Mr. Orszag's analysis as true (it is not), competing expert methodologies are not a sufficient basis to exclude opinions under *Daubert. See Allapattah Services, Inc. v. Exxon Corp.*, 61 F. Supp. 2d 1335, 1354 (S.D. Fla. 1999) ("[T]he opinions of both experts are well within the range where experts may honestly differ, and where the jury must decide among their competing points of view.").

Furthermore, to confirm his regressions analyses, Dr. Cutler relied on publicly available data and information to show that "the youth market for e-cigarettes had reached equilibrium in early 2017, with the inflow of new youth vapers equal to the outflow of youth quitting or becoming adults and no further increase in the youth vaping rate expected." JLI Ex. 4, Cutler Rpt., ¶ 153. The results are set forth in his Exhibit 24 (id.), which shows an illustrative example of vaping rates post-2017 had they been constant as of 2017. JLI is certainly free to make claims about what the publicly available data may otherwise show, but that is not grounds to justify exclusion. ¹⁶

Taken together, the entirety of Dr. Cutler's causal analyses with respect to JLI—all of which are based on basic and well-established economic methodologies—collectively establish that JLI's misconduct has causally increased youth vaping rates. And Dr. Cutler never acknowledged his causation analysis is not the product of econometric analyses as JLI wrongfully contends. Indeed, as summarized by Dr. Cutler in his deposition regarding these three analyses set forth in his report:

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¹⁵ Altria also retained an economist to challenge Dr. Cutler's opinions, for a total of five economists that respond to Dr. Cutler.

¹⁶ JLI also argues that Dr. Cutler ignored adult vaping rates in his various analyses. As explained in detailed herein, this straw-man argument is unpersuasive and ultimately has no bearing on Dr. Cutler's analysis. Simply put, Dr. Cutler is focusing on the impact of JLI's misconduct on youth vaping, not adult use of e-cigarettes.

Q. Can you explain to the court whether there is a term of art in economics that describes these type of analyses?

A. Yeah. These are often called an indirect model. And so, I have used them before in my research, and other people have used them before in research, and what you're trying to do is say, in a situation where I cannot control for something directly, because the time period isn't long enough or I don't have the data, let me do it indirectly by trying to say, can I rule out all the other relevant things that might be going on, and so, this is actually a fairly common methodology that people use.

See JLI Ex. 33, Cutler Dep. at 389:11-25. Dr. Cutler further confirmed that he "regularly use[s] this method in attempting to identify a causal relationship in an economic or econometric manner." *Id.* at 390:4-11. Thus, Dr. Cutler's use of these different economic and econometric methodologies is perfectly reasonable and reliable. At best, JLI's arguments and Mr. Orszag's opinions which it bases its motion upon go to the weight and certainly do not justify the exclusion of Dr. Cutler's but-for analysis under *Daubert*.

e. <u>Dr. Pratkanis's Opinions Are Reliable</u>

Dr. Pratkanis provides ample support for his opinion that "JLI caused a youth vaping epidemic." (JLI Mot. 1 at 40-43.) This opinion is consistent with conclusions drawn by government agencies (*see* Section V.C.1.d., *supra*), which themselves support the reliability of his opinion. JLI's critiques are fodder for cross-examination, but none raise a legitimate *Daubert* concern.

Dr. Pratkanis devotes nearly 50 pages of his report to explaining his causation analysis. JLI Ex. 17, Pratkanis Rpt. at 60-108. He opines that JLI's addictive JUUL product, the use of mild nicotine salts, the marketing of JUUL as a tech lifestyle product, and the USB-like design all led JUUL to drive the massive increase in youth vaping. *Id.* at 61. The Surgeon General's report and the scientific literature support this conclusion. *Id.* at 61-63. For instance, one study showed that people aged 15-17 were 16 times more likely to be JUUL users than those aged 25-34. *Id.* at 63. Dr. Pratkanis then analyzes how JLI's marketing created this expanding customer base, through its "diffusion of innovation" model. Through ad campaigns and social media, JLI transmitted its unique selling proposition—that JUUL is a tech lifestyle product that satisfies. The message

increases awareness, which leads to an increasing number of customers—and in this case, youth—trying the product and becoming addicted. *Id.* at 63-65.

As Dr. Pratkanis explains, a causation analysis requires three steps. *Id.* at 67. Here, there is a relationship between two variables—JLI's efforts and JUUL sales; there is evidence that one variable (JLI's marketing) preceded the other (the rise in youth vaping); and there must not be strong evidence of a third variable as the alternative cause. *Id.* In conducting that causation analysis, Dr. Pratkanis relies on scientific criteria developed by Bradford Hill. *Id.* These criteria are commonly used in causation analyses. *See In re Viagra (Sildenafil Citrate) & Cialis (Tadalafil) Prod. Liab. Litig.*, 424 F. Supp. 3d 781, 795 (N.D. Cal. 2020) ("There is no dispute that, as a general proposition, Bradford Hill analysis is a reliable and accepted method for determining causation."). Dr. Pratkanis analyzes the nine Bradford Hill criteria and determines that JLI's marketing drove the JUUL youth vaping epidemic. JLI Ex. 17, Pratkanis Rpt. at 67-69. Dr. Pratkanis then explains in great detail, citing scientific literature and JLI's documents, how JLI used parties, social media, influencers, and other methods to spread its message, leading to extensive youth use of JUUL. *Id.* at 69-96. Next, he explains the importance of JLI gaining prominent retail space. *Id.* at 96-102. Finally, he explains how he ruled out alternative explanations for the youth vaping epidemic. *Id.* at 102-08. It is a thorough analysis—a far cry from the "junk science" that *Daubert* seeks to exclude.

JLI argues that the Bradford Hill criteria have not been used in this specific context, but it cites no literature or case law suggesting that the criteria must be limited to medical analysis or any other context. (JLI Mot. 1 at 40-41.) JLI next asserts that Dr. Pratkanis did not use any "scientific methods," and that he only "remarks on the correlation of events." (*Id.* at 41.) But Dr. Pratkanis's analysis relies on the Bradford Hill criteria, the scientific literature, JLI's documents, and his own expertise to explain **how** JLI used various marketing channels to appeal to youth. *See* Ex. 17, Pratkanis Rpt. at 60-108.

JLI also claims that Dr. Pratkanis uses assumptions that "are either unjustified or incorrect." (JLI Mot. 1 at 41.) Those are contentions for cross-examination. The Bradford Hill test emphasizes relationships that can be used to infer causation, *see* JLI Ex. 17, Pratkanis Rpt. at 67-68, which provides the "basis" for how JLI's marketing "impacted youth." (JLI Mot. 1 at 41.) And while JLI

criticizes Dr. Pratkanis for assuming that its marketing was "consistent," Dr. Pratkanis does not offer that opinion. *See* JLI Ex. 17, Pratkanis Rpt. at 67 (referring to how "consistently" a relationship is observed, not the consistency of JUUL marketing). Dr. Pratkanis never opines that JLI's marketing imagery was uniform; rather, he explains that the campaigns consistently reinforced JUUL's unique selling proposition, as a tech lifestyle product that satisfies. *See Id.* at 14.

Lastly, JLI claims Dr. Pratkanis failed to account for youth e-cigarette usage before JUUL came to market, or for alternative causes for the youth vaping epidemic. (JLI Mot. 1 at 41-42.) These are topics for cross-examination. Whether youth vaping was an issue before JUUL is irrelevant to whether JUUL caused a massive increase in youth vaping—which it did. JLI Ex. 17, Pratkanis Rpt. at 61-63; *see also* JLI Ex. 10, Halpern-Felsher Rpt. at 163 ("JUUL's role in the youth vaping epidemic has been stated by numerous health and governmental organizations including the FDA and CDC."). Dr. Pratkanis also cites academic literature showing that sales did not increase for competing products when youth usage was exploding. JLI Ex. 17, Pratkanis Rpt. at 67-68. And, as noted, Dr. Pratkanis devotes an entire section of his report to addressing alternative causes. *Id.* at 102-08. If JLI disagrees with that analysis, it is free to cross-examine Dr. Pratkanis.

f. Plaintiffs' Experts Need Not Rule Out Alternative Causes of Underage Use

Lastly, JLI asserts that Drs. Grunberg, Halpern-Felsher, Proctor, and Emery did not consider other possible causes for the rise in youth usage. As with JLI's other causation arguments, this contention is misguided as a matter of law.

As noted above, an expert's analysis need not definitively *prove* an element of the case, such as causation. *See* Section V.D.3.b., *supra*. With respect to causation, even at trial plaintiffs will need to show that the conduct was a "substantial factor" or, in the case of the class UCL claim, that the money or property "may have been acquired" by the defendant as a result of the alleged conduct (which does not entail a showing of but-for causation). *See* Section V.D.1., *supra*. It follows, therefore, that the analysis need not definitively exclude other potential causes. *See Hemmings v. Tidyman's Inc.*, 285 F.3d 1174, 1188–89 (9th Cir. 2002) ("[T]he law does not require

the near-impossible standard of eliminating all possible non-discriminatory factors ... We cannot say that the exclusion of preferences, individual qualifications, and education rendered the data set so incomplete 'as to be irrelevant.") (citation omitted).

Any argument about how precisely to weigh other potential causal factors goes to the weight of the expert testimony, not its admissibility. *See, e.g., Paoli*, 35 F.3d at 744 (stating that there can be "good grounds for an expert's conclusion even if the judge thinks that there are better grounds for some alternative conclusion"); *Evers*, 2021 WL 3710735, at *10 (noting that a party "may probe what materials were not reviewed on cross-examination and may challenge an expert's conclusions by referencing evidence not taken into consideration"); *Salas v. Toyota Motor Sales, U.S.A., Inc.,* No. CV 15-8629 FMO (EX), 2017 WL 11247885, at *5 n.9 (C.D. Cal. Sept. 29, 2017) (holding that expert "was not required to rule out other causes"); *United States ex rel. Jordan v. Northrop Grumman Corp.*, No. CV 95-2985 ABC (EX), 2003 WL 27366252, at *6 (C.D. Cal. Mar. 10, 2003) (noting, in denying motion to exclude expert testimony for failing to eliminate alternative causes that the defendants "will have the opportunity to cross-examine [the expert] on the plausibility of alternative causes" at trial).

As JLI's own case notes, "failure to address alternative theories is not necessarily a basis for exclusion" unless the testimony "wholly disregards other studies or data that undermine the expert's position." *Chung v. Washington Interscholastic Activities Ass'n*, No. C19-5730-RSM, 2021 WL 1978698, at *3 (W.D. Wash. May 18, 2021) (excluding expert testimony on the financial cost of shifting state tennis championship tournaments from Saturdays to other days of the week as irrelevant and unreliable because the expert "ignore[d] a body of academic literature undermining his position that different attendance rates at athletic games are driven primarily by the day the competition is scheduled," *id.* at *4); *see also Carnegie Mellon Univ. v. Hoffmann-LaRoche, Inc.*, 55 F. Supp. 2d 1024, 1036 (N.D. Cal. 1999) (excluding testimony of expert who "fail[ed] to consider the relevant scientific literature"). And this is hardly a case where Plaintiffs' experts "neither explain the methodology the experts followed to reach their conclusions nor point to any external source to validate that methodology." *Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1319 (9th Cir. 1995).

4. <u>Plaintiffs' Experts Provide Reliable Opinions Concerning the Chain of Causation for Virality</u>

Finally, JLI argues that unspecified portions of Plaintiffs' marketing experts' analysis of the viral spread of JUUL's marketing must be excluded as unreliable. Each of JLI's criticisms about virality properly go to the weight of the opinions and should be considered, if at all, by the jury.

Plaintiffs' experts' marketing opinions are not unreliable because they address both JLI's own marketing materials and user-generated content about JUUL. Contrary to JLI's insistence, (see JLI Mot. 1 at 44-46), there is no misdirection in the expert analysis of JUUL's spread on social media. The distinction between content *created* by JLI's marketing team and content *inspired* by JLI's marketing is central to the point, made by several experts, that JLI took deliberate action to harness *both* earned media and user-generated content because they are powerful marketing tools. See, e.g., JLI Ex. 3, Chandler Rpt. at 5-6 (JLI understood that earned media can "amplify their message and foster hyper-growth of their markets" at very little cost, because "once a product is seeded in fertile ground, the advertising will be generated automatically" and "[w]hen marketing on this scale works, it can acquire the momentum of a snowball running downhill, picking up audience members who, in turn, will share that content"); JLI Ex. 17, Pratkanis Rpt. at 17-23 (describing "diffusion of innovation" model).

At core, JLI argues that experts cannot rely on third-party posts on social media because they break the chain of causation between its actions and Plaintiffs' injuries, so Plaintiffs would be holding it "vicariously liable" for third party conduct if those posts are included. (JLI Mot. 1 at 46 (quoting *Colgate*, 402 F. Supp. 3d at 760)). But this is not vicarious liability. Under the basic tenants of tort law, JLI may be responsible for the natural and foreseeable consequences of its actions. *See generally*, Rest. 2d Torts §§ 433-35, 439 (1965) (describing rules of causation); *id.* §§ 440-43 (describing the defense of superseding cause). The relevant conduct by third parties—spreading JLI's marketing messages over social media in precisely the way JLI's marketing team planned and

¹⁷ This section of JLI's motion includes reference to the opinions of Emery, Jackler, Chandler, Wooley, Drumwright, Pratkanis, and Cutler, though the particular opinions it seeks to exclude for each is not clearly identified. (*See* JLI Mot. 1 at 44-49). But other experts, for example Dr. Halpern Felsher, also discuss JUUL's viral marketing but are not addressed in JLI's motion.

intended—does not break the chain of causation because it is neither independent of nor an unforeseeable result of JLI's actions. *See, e.g., Exxon Company v. Sofec, Inc.*, 517 U.S. 830, 837 (1996) (superseding cause is "a later cause of independent origin that was not foreseeable"); Rest. 2d Torts § 443 ("The intervention of a force which is a normal consequence of a situation created by the actor's negligent conduct is not a superseding cause of harm which such conduct has been a substantial factor in bringing about."). For this reason, the volume of social media interaction with JUUL, including third-party content, is properly considered, and need not be excluded.

JLI next insists that the virality opinions unreliably conclude that JUUL marketing caused the viral spread, pointing to the time between the purported end of the worst-offending Vaporized campaign in 2015 and JUUL's exponential rise in popularity in 2017 (JLI Mot. 1 at 46-48.) First, as Plaintiffs' experts discuss, Vaporized lasted longer than five months in 2015. *See* JLI Ex. 11, Jackler Rpt. at 248-58 (

here inciting action by the company. *E.g.*, JLI Ex. 7, Emery Rpt. at 34 (a delayed effect is "exactly how viral messaging works. After a slow build, the amount of messaging increases exponentially"). Dr. Cutler explains that "[e]ven temporary misconduct in the market for vaping products can have long-term consequences for youth vaping and smoking," for four reasons: 1) vaping products are addictive, so it's easier to start than stop; 2) misconceptions about the product are difficult to change; 3) youth are sensitive to peer behavior, so use by some youth generates later use by others; and 4) misconduct creates "thick markets" (with many buyers and sellers), and "[m]ore users means greater opportunity to borrow or purchase a vaping device, making initiation much easier." JLI Ex. 4, Cutler Rpt. at 5-6, 39-52.

Finally, JLI argues that Plaintiffs' experts do not have the precise type of "scientific" evidence that JLI claims is necessary to prove beyond any doubt that JUUL's viral spread was actually caused by JLI marketing, and in turn caused underage use. (JLI Mot. 1 at 48-49.) Once again, JLI's artificially constructed hurdles do not justify the exclusion. Experts need not eliminate all possible alternative explanations or use only one type of scientific evidence; they need only to

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present reliable and helpful opinions. See, e.g., Pyramid Techs, 752 F.3d at 816 (expert opinion admissible where it allows a jury to "reasonably infer causation from [the expert's] report and other evidence"). Plaintiffs' experts explain the marketing techniques JLI used to foster engagement on social media and how those techniques worked precisely as JLI expected and intended to increase youth usage. See, e.g., JLI Ex. 10, Halpern-Felsher Rpt. at 62-71 (Studies on youth nicotine use have consistently concluded that advertising contributes to underage usage); JLI Ex. 18, Prochaska Rpt. at 62 ("Strong empirical evidence indicates that tobacco companies' advertising and promotions affect ... attitudes about smoking, intentions to use, and actual smoking behavior."); see also JLI Ex. 7, Emery Rpt. at 7 ("JUUL used promotional strategies that have been shown to appeal to youth and have been banned for over 25 years for cigarette promotion"); JLI Ex. 11, Jackler Rpt. at 19 (same); JLI Ex. 18, Pratkanis Rpt. at 109 (same). And, just as tobacco advertising has been shown to contribute to youth usage generally, Plaintiffs' experts cite evidence that viral JUUL marketing through social media—in combination with other aspects of JUUL marketing and product design—greatly contributed to widespread youth JUUL use. See, e.g., JLI Ex. 7, Emery Rpt. at 7-8, 65-66; JLI Ex. 4, Cutler Rpt. at 4-5 ("JUUL has an outsized role in the vaping crisis"); JLI Ex. 18, Pratkanis Rpt. at 5-6, 60-108; JLI Ex. 29, Woolley Rpt. at 87-88; JLI Ex. 11, Jackler Rpt. at 379-99. JLI's criticism that Plaintiffs' experts lack empirical data and quantitative studies that fully eliminate alternate causes for the youth vaping epidemic should be considered by a jury in connection with the weight to give the experts' opinions.

Plaintiffs' Experts Have Sufficient Foundation to Opine that JUUL Ε. Marketing Caused Plaintiff B.B. to Use the Product at Age 12.

This Court also should reject JLI's arguments regarding the case-specific marketing opinions of experts Grunberg, Levy, Winickoff, and Prochaska¹⁸ related to the B.B. bellwether case. JLI advances two arguments, both are without merit.

First, none of these experts relied on a false premise in determining that JUUL marketing influenced B.B.'s decision to use JUUL. JLI claims that the experts' opinions should be entirely

¹⁸ JLI also notes Dr. Casey's case-specific opinion but does not challenge it directly. (See JLI Mot. 1 at 49-51).

disregarded based on a comment that 16-year-old B.B. made at her deposition: stating that she did not "pay attention" to advertisements she had seen for JUUL. (JLI Mot. 1 at 50). But B.B.'s additional testimony shows that JUUL advertising made a substantial impression on her.¹⁹

B.B. started vaping at age 12. JLI Ex. 19, Prochaska Rpt. (BB) at 6. Before she began, she viewed JUUL advertising, marketing, and product packaging at convenience stores in and near her hometown of McMinnville, Tennessee. Pltf. Ex. 7, B.B. Decl. at ¶ 2. Some of the display cases she saw on store counters contained video screens that played a video of young-looking individuals dancing and using JUUL products. *Id.* at ¶ 5. Although these advertisements did not expressly state that JUUL was safe, B.B. testified that "they kind of gave [her] the impression they're safe, just the way they're set up, the way they look, the colors." Pltf. Ex. 8, B.B. Dep. at 118:2-12. B.B. explained that the different colors used in JUUL advertisements made JUUL look like something fun. *Id.* at 118:13-17. Images of JUUL devices with everyday items such as computers furthered her belief that JUUL was safe. *Id.* at 118:18-23.

The friend who offered B.B. her first JUUL, E.S., was 13 or 14 years old. *Id.* at 74:23-75:6; Pltf. Ex. 9, E.S. Dep. at 103:2-14. E.S. was exposed to JUUL advertising at stores and on Instagram. Pltf. Ex. 9, E.S. Dep. at 105:16-108:23. None of that advertising led her to believe that JUUL was harmful or addictive. *Id.* at 109:3-12. Thus, both B.B. and her initial source were exposed to JUUL advertising and gained the impression that JUUL was a safe, fun product.

None of these facts contradict the expert opinions identified in JLI's motion. Drs. Grunberg and Winickoff testified that B.B. was exposed to JUUL advertising at convenience stores. (JLI Mot. 1 at 50). As laid out above, those assertions are accurate. Dr. Prochaska is quoted as saying that B.B. "observed JUUL advertising in her town, which made the product appear safe." (*Id.*). Again, B.B.'s testimony supports this statement. If B.B. made other statements that JLI believes are contradictory, then those are points for cross-examination, not exclusion. Certainly, this is not a circumstance where "**indisputable** record facts contradict or otherwise render the opinion unreasonable," as JLI claims. (*Id.* at 50 (citing *Brooke Grp. Ltd. v. Brown & Williamson Tobacco*

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¹⁹ B.B.'s addiction history is laid out in more detail in response to Defendants' summary judgment motion, and that response is incorporated by reference here.

Corp., 509 U.S. 209, 242 (1993) (emphasis added)). Where, as here, the facts that underlie an expert's opinion are disputed, the issue is for the jury. See Primiano, 598 F.3d at 567–68 (overturning exclusion of expert opinion that would have helped jury to resolve fact dispute). Rule 702 requires that opinions be based on "sufficient" facts or data, not "undisputed" facts or data. Fed. R. Evid. 702(b). The opinions at issue here meet that standard.

The experts also have a reliable foundation for their opinions. JLI mischaracterizes their opinions in trying to claim otherwise as to experts Grunberg, Prochaska and Levy. For instance, JLI claims that Dr. Prochaska has a "one-sentence" opinion connecting JUUL's marketing with B.B.'s use. (JLI Mot. 1 at 51). This is patently false. Her report lays out seven categories of sources for her case-specific opinions. JLI Ex. 19, Prochaska Rpt. (BB) at 3. She also interviewed B.B. *Id.* at 5. In a long, detailed paragraph, Dr. Prochaska laid out how B.B. started vaping, including that she trusted the friend who suggested it, and that the JUUL ads she saw in retail stores "made me feel like it was more safe, seeing it everywhere." *Id.* at 6-7. Further, she did not know that the product contained nicotine, was addictive, or was otherwise harmful. *Id.* Those details, and many others in the report, inform Dr. Prochaska's ultimate opinion that "Defendants' conduct in designing, marketing, flavoring, promoting, selling, and manufacturing JUUL initiated and sustained [B.B.'s] addiction to nicotine" *Id.* at 12.

Dr. Levy similarly provides a detailed explanation in her report connecting JLI's marketing to B.B.'s use. *See* JLI Ex. 14, Levy Rpt. (BB) at 9-10. Unable to attack her broadly, JLI tries to nitpick her opinions—claiming, for instance, that she did not delineate which specific warnings B.B. saw. (JLI Mot. 1 at 51). As Dr. Levy explained, the sources are listed in her report, and she considered that information in her diagnostic formulation. JLI Ex. 43, Levy Dep. at 58:18-59:25, 61:5-20. That issue, and the issue about whether Dr. Levy evaluated all possible factors, (JLI Mot. 1 at 51), are classic issues for cross-examination. *See United States v. Rite Aid Corp.*, No. 212CV01699KJMEFB, 2020 WL 3970201, at *10 (E.D. Cal. July 14, 2020) (stating that "[t]he *Daubert* standard does not exist to ensure that only the most ideal scientific evidence is admissible"); *Curry v. Contra Costa Cnty.*, No. 12-CV-03940-WHO, 2014 WL 4311321, at *2

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(N.D. Cal. Aug. 29, 2014) (Orrick, Dist. J.) (allowing opinions, subject to "vigorous cross," even though expert's opinions were "potentially speculative").

Dr. Grunberg, meanwhile, incorporated his general report on marketing into his case-specific report. JLI Ex. 9, Grunberg Rpt. (BB) at 1. He used that information and the testing he did on B.B. to reach his opinions, including that "[B.B's] initiation of JUUL and the harms from using JUUL were the result of Defendants' conduct related to JUUL, including designing, marketing, flavoring, promoting, manufacturing JUUL products, as set forth fully in my general report." *Id.* at 3. He did not, as JLI contends, ignore his own principles as stated in an article 17 years ago. (JLI Mot. 1 at 51). The psychological factors that lead to addiction are discussed in Dr. Grunberg's general report, with the drug itself being paramount, and those apply to B.B. *See* JLI Ex. 38, Grunberg Dep. at 572:10-574:5 ("I don't have to say the name of every single plaintiff when I say, [a]II of the variables that are described and discussed ... are relevant to Ms. Bain, as I refer to in this report.").

There is sufficient foundation for all case-specific opinions offered by Plaintiffs' experts, and the issues raised by JLI merit cross-examination, not exclusion.

F. The Experts' Opinions About JLI's Inadequate Youth Prevention Programs are Relevant and Reliable, and all Experts are Qualified to Give Their Stated Opinions.

This Court also should reject JLI's efforts to exclude opinions about JLI's inadequate youth prevention efforts. JLI's first argument is absurd because it claims that opinions about youth prevention efforts do not "fit" the case—i.e., they are not relevant. Given the importance of youth vaping to Plaintiffs' claims, it is illogical to claim that opinions about youth prevention efforts are irrelevant. *See*, *e.g.*, *Fujifilm*, 2015 WL 1737951, at *10 (holding that challenges to relevance went to weight, not admissibility). JLI's arguments about qualifications and reliability also lack merit.

1. <u>JLI's Fit Argument Mischaracterizes the Experts' Opinions.</u>

This Court should reject JLI's "fit" argument, which is based on a false premise. JLI's argument is illogical because the inadequacy of JLI's youth prevention programs is clearly a

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relevant issue.²⁰ JLI also inaccurately claims that Plaintiffs' experts believe JLI is bound by the tobacco MSA. They do not. Instead, these experts are using the MSA as a guide on how to avoid marketing tobacco products to youth.

JLI claims that 11 of Plaintiffs' experts opine "that JLI was obliged to follow the terms of the MSA in its youth prevention efforts and that it failed to do so." (JLI Mot. 1 at 52). But Plaintiffs' experts made it clear that they were not treating the MSA as a legal requirement. JLI even quotes several experts as acknowledging that the MSA does not apply to JLI—thereby undercutting its own argument. (*See Id.* at 53). For instance, Dr. Drumwright's report states that "JUUL was not a party to the [MSA] and, therefore, was not bound by it in a strictly legal or technical sense." JLI Ex. 5, Drumwright Rpt. at 80. No expert claims otherwise.

The MSA does, however, provide a standard for any company trying to avoid marketing tobacco products to youth. As Dr. Drumwright explains:

Thus, JUUL clearly viewed itself as needing to abide by the spirit, if not the letter, of the standards and prohibitions set out in the MSA.

Id. Dr. Jackler described the MSA as providing "relevant marketing guidelines." JLI Ex. 11, Jackler Rpt. at 374. JLI executives were well aware of the terms and prohibitions in the MSA. JLI Ex. 10, Halpern-Felsher Rpt. at 64.²¹

Although JLI was not bound by the MSA, it sets an industry standard with regard to youth marketing. The MSA provides a road map for ways to avoid marketing tobacco products to children. *See Id.* & n.83; JLI Ex. 5, Drumwright Rpt. at 29-30. Thus, the MSA is a great resource

²⁰ JLI appears to be arguing that these opinions are always irrelevant, as opposed to being irrelevant to B.B.'s case. The failure of youth prevention efforts has clear relevance to the litigation. To give just one example, these issues would be relevant to any case in which a minor purchased JUUL online, thereby avoiding JLI's age-gating efforts.

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for a company seeking to avoid marketing to youth, or for a jury in evaluating whether a company did so.

JLI Ex. 7,

Emery Rpt. at 31-32

This is further

evidence that the MSA helps to establish the industry standard.

There is nothing improper about experts relying on industry standards in evaluating whether a company acted responsibly. *See, e.g., Hangarter*, 373 F.3d at 1016–17 (rejecting argument that such testimony improperly stated a legal conclusion). This issue arose recently in this District in the Elizabeth Holmes trial, as Ms. Holmes attempted to exclude evidence of industry standards. The court rejected that argument, noting that an expert "is not prohibited from testifying about industry standards … merely because federal regulations form part of those standards." *Holmes*, 2021 WL 2035177, at *4. The court further held that the expert's testimony about industry standards would not constitute legal conclusions, would be helpful to the jury, and would not mislead the jury. *Id.* at *4-5.

This Court should reach the same conclusions here. There is no reason to assume that testimony about the MSA will confuse or mislead the jury, as JLI proposes. (JLI Mot. 1 at 54). Plaintiffs' experts clearly state that JLI was not required by law to follow the MSA. (*Id.* at 53). The experts will explain to the jury why the MSA is an important guideline. The Court could issue a limiting instruction if it has that concern in a particular trial. *Apple iPod iTunes Antitrust Litig.*, No. 05-CV-0037 YGR, 2014 WL 4809288, at *8 (N.D. Cal. Sept. 26, 2014). But the Court should not exclude evidence as "confusing" for every future trial. The context of how the evidence will be used is necessary to make that determination. *Cf. In re Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, No. MDL 2327, 2016 WL 8788207, at *2 (S.D.W. Va. Aug. 26, 2016) (MDL Court reserving some issues for trial because "my interest in accuracy counsels reserving ruling until the reliability of the expert testimony may be evaluated at trial").

JLI's "fit" argument should be rejected.

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2. All Experts are Qualified to Give Their Stated Opinions.

This Court also should reject JLI's attacks on the opinions of experts Halpern-Felsher, Drumwright, Jackler, and Ribisl regarding JLI's "youth prevention" programs. As to all but Dr. Ribisl, JLI attacks the experts' qualifications.

Rule 702 lists several ways in which an expert may be qualified: "by knowledge, skill, experience, training, or education." Fed. R. Evid. 702. "The qualification standard is meant to be broad and to seek a 'minimal foundation' justifying the expert's role as an expert." Allen v. Am. Cap. Ltd., 287 F. Supp. 3d 763, 776 (D. Ariz. 2017) (citing Hangarter, 373 F.3d at 1015–16; Thomas v. Newton Int'l Enters., 42 F.3d 1266, 1269 (9th Cir. 1994)). All Plaintiffs' experts are qualified to give the opinions they offer.

Dr. Drumwright is clearly an expert in marketing—JLI does not contend otherwise—and that is where she has focused her opinions. She did not opine specifically about JLI's ageverification system, so it is immaterial whether she is an expert in that technology. (See JLI Mot. 1 at 54.) See also JLI Ex. 5, Drumwright Rpt. at 6-11 (listing Dr. Drumwright's opinions). She opines that she saw no evidence of JLI increasing its age verification capabilities when it launched the product. JLI Ex. 34, Drumwright Dep. at 211:12-23. If JLI believes that she is incorrect, it is free to cross-examine Dr. Drumwright.

Dr. Halpern-Felsher also is not opining about JLI's technology. She opines about the need for age verification systems, about steps JLI did not take, and about reports that children were able to buy JLI's product on the internet. JLI Ex. 10, Halpern-Felsher Rpt. at 110-13. For instance, she relies on evidence that JLI was not using all fraud protection services offered by its age verification provider, Veratad. Id. at 112. As a developmental psychologist, Dr. Halpern-Felsher has a unique understanding of why age-gating technology is important. JLI Ex. 39, Halpern-Felsher Dep. at 67:13-68:3.

JLI's only criticism of Dr. Jackler's qualifications is that he is a medical doctor. (JLI Mot. 1 at 55). JLI conveniently ignores that tobacco marketing has been Dr. Jackler's primary research area for more than fifteen years. JLI Ex. 11, Jackler Rpt. at 9. Dr. Jackler is well familiar with the scientific literature and has published numerous peer-reviewed articles, including articles about the

initiation of nicotine addiction. *Id.* at 12; JLI Ex. 40, Jackler Dep., at 143:15-144:5. He is, therefore, qualified at least by education and knowledge on these topics.

3. The Experts Reliably Evaluated JLI's Youth Prevention Efforts.

The experts under attack used reliable methods in reaching their opinions about youth prevention. Continuing its pattern, JLI focuses on what the experts might have done, rather than analyzing what they actually did. JLI criticizes the experts for failing to use objective measures of success or conduct empirical studies. (JLI Mot. 1 at 55-56).

These experts' opinions do not lack reliability simply because they cannot quantify with numerical precision the impact that better youth prevention efforts might have had. As noted, studies are not necessary for an opinion to be valid. *See* Section V.A., *supra*. Second, these experts have pointed to the MSA as an industry standard, as discussed above. *See*, *e.g.*, JLI Ex. 7, Emery Rpt. at 31-32. Their methodology has been to study the evidence in the case and apply their specialized knowledge to that evidence. *See NAACP*, 504 F. Supp. 3d at 517 (stating that in the social sciences field "experience is the predominant, if not sole, basis for a great deal of reliable expert testimony").

For instance, Dr. Drumwright explained how one can extrapolate from the traditional cigarette industry that youth prevention efforts lead to declines in nicotine use by children. JLI Ex. 34, Drumwright Dep. at 234:4-15. Dr. Halpern-Felsher testified that there is "a huge amount of literature that's very, very well known in the field that would tell us that it would be substantial, that if youth were not exposed to any form of marketing ... they would be significantly less likely to initiate and continue to use a tobacco product. I mean, that's the basis of the MSA." JLI Ex. 39, Halpern-Felsher Dep., at 76:2-20. Dr. Jackler explained that empirical studies are not the only way to measure success, and that there is ample evidence that JUUL marketing appealed to youth. JLI Ex. 40, Jackler Dep. at 209:1-211:18. That point is the focus of these experts' opinions—that JLI's marketing led to the youth vaping epidemic. The failure of JLI's youth prevention efforts supports those primary opinions. *See*, *e.g.*, JLI Ex. 5, Drumwright Rpt. at 6-11 (summary of opinions), 106-07 (noting JLI's youth prevention plans in 2020 and opining that they could have been implemented sooner).

Only Dr. Ribisl focuses squarely on JLI's youth prevention efforts. Unable to challenge his qualifications, JLI pieces together quotes from counsel that do not appear on the cited pages. (*See* JLI Mot. 1 at 56.) *See also* JLI Ex. 51, Ribisl Dep. at 160:2-161:9. As Dr. Ribisl explained, "efforts to reduce youth access through commercial sources, online retail, will reduce youth initiation and use of e-cigarette products. But I did not quantify the specific amount by which it would reduce it." *Id.* at 161:3-9. Dr. Ribisl further explained that his opinions are based on "decades of studies on youth access" at Stanford University, where he did his postdoctoral training and continues to work. *Id.* at 167:6-15. Thus, his opinions are based on "science and evidence about how to reduce youth access and how to reduce youth initiation of products like JUUL products." *Id.* at 167:15-18.

G. Conclusion

For all the foregoing reasons, JLI's Motion to exclude Plaintiffs' experts' marketing opinions should be denied.

VI. JLI MOTION #2: ADDICTION

JLI seeks to exclude opinions regarding: i) JUUL's addictiveness, including those comparing JUUL's nicotine delivery characteristics with combustible cigarettes and nicotine cessation products; ii) the role of flavors in youth uptake and addiction; and (iii) product features that result in variable nicotine spikes. (*See generally JLI Mot. 2*). JLI argues that these opinions are irrelevant or unreliable, but its arguments are meritless.

Under Rule 702 and *Daubert*, Plaintiffs' experts' opinions about JUUL's addictiveness are admissible. These experts, whose qualifications JLI does not challenge, have decades of experience in their fields, and their extensive knowledge provides a reliable foundation for opinions about addictiveness and abuse liability. For instance, Dr. Shihadeh founded the American University of Beirut's Aerosol Research Laboratory and regularly serves as an expert to the World Health Organization's Study Group on Tobacco Product Regulation. JLI Ex. 23, Shihadeh Rpt. at 2-4. Dr. Prochaska is director of Stanford University Cancer Center's Tobacco Treatment Service, where she treats patients suffering from nicotine addiction, including JUUL users. JLI Ex. 18, Prochaska Rpt. at 1. Dr. Eissenberg is the Co-Director of the Center for Study of Tobacco Products at Virginia Commonwealth University and has spent two decades as an independent researcher of

the physiological, subjective, and behavioral effects of novel tobacco products. JLI Ex. 6, Eissenberg Rpt. at 4-11. And, Dr. Grunberg is a Professor of Medical and Clinical Psychology and Professor of Neuroscience at the Uniformed Services University of Health Sciences, who has provided consultation to the Department of Defense, National Institutes of Health, and the FDA regarding nicotine addiction, tobacco use, and behavioral health. JLI Ex. 8, Grunberg Rpt. at 1, 4-10.

These experts' opinions also are relevant to issues central to this MDL, and to Plaintiff B.B.'s bellwether case, including JLI's design, marketing, and sale of a highly addictive nicotine product, and its targeting of youth. Plaintiffs' experts extensively analyzed the facts and data relevant to their opinions, including their own and others' peer-reviewed studies, and employed recognized methodologies for assessing addictiveness and abuse liability. Thus, the Court should reject JLI's arguments in Motion #2.

JLI tries to undercut these relevant and reliable arguments by applying the wrong standards and then attacking Plaintiffs' experts for failing to meet these improper standards. The Tobacco Control Act ("TCA") and the FDA do not set the standard for admission of expert testimony in this litigation. JLI also claims that only a formal abuse liability assessment ("ALA") may be used to determine a product's addictiveness. Yet, experts routinely opine about addictiveness without such a formal assessment, including JLI expert Dr. Jack Henningfield. JLI's Motion #2 should be rejected in its entirety.

A. Rule 702 and *Daubert*—not the Tobacco Control Act—Govern the Admissibility of Expert Testimony.

JLI insists that the TCA and PMTA set the "legal standard" for admissibility of expert opinions on the addictiveness of tobacco products. (JLI Mot. 2 at 6). JLI spends several pages discussing the TCA and PMTA, focusing on the PMTA process and the information JLI believes is relevant to a PMTA for a new ENDS device. JLI then argues that Plaintiffs' experts' opinions regarding the addictiveness of JUUL products should be excluded because those experts "applied an erroneous legal standard that is outside the bounds of ... the TCA." (*Id.*). But JLI incorrectly conflates two separate standards—the standard for obtaining FDA authorization to market a JUUL

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product and the standard for admission of expert testimony in litigation. It is a classic strawman argument: JLI identifies the wrong standard and seeks to exclude Plaintiffs' experts for failing to meet it. Rule 702 governs the admissibility of expert witness testimony. *See* Fed. R. Evid. 702. That the products at issue in this MDL are subject to certain federal regulations does not change that fact.²²

Evidence is relevant if it "will assist the trier of fact to understand or determine a fact in issue." Maldonado v. Apple, Inc., 2021 WL 1947512 at *2 (N.D. Cal. May 14, 2021) (quoting Cooper v. Brown, 510 F.3d 870, 942 (9th Cir. 2007)). Relevance of expert opinion is, thus, defined by the parties' claims and defenses, not the TCA or PMTA. *Primiano*, 598 F.3d at 567. Defendants cite no case applying the "standard" they propose, because there are no such cases. This case is not about JLI's PMTA seeking the FDA's authorization to market JUUL, and the jury will not rule on that application. Indeed, JLI previously attempted to confine Plaintiffs' claims to the TCA and the FDA's evaluation of JLI's PMTA. In rejecting those arguments, the Court noted the "likely limited relevance of the FDA's actions" concerning JLI's PMTA, stating: "Whatever action it takes on JLI's PMTA, the FDA will not affect, much less resolve, the bulk of plaintiffs' liability theories based on JLI's and the other defendants' past conduct." (ECF No. 1084 ("First MTD Order") at 16-17). This Court held: "[T]he technical and policy questions that will be addressed by the FDA do not supplant the legal and fact-based issues to be resolved by [the Court] or a trier of fact." (Id.). Ironically, JLI argued previously in this MDL that the TCA **did not** apply to JUUL products before the deeming date. In any event, neither JLI's pending PMTA nor the TCA generally supplants the Daubert analysis.²³

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²² Federal regulations remain relevant to the case as a whole. For example, JLI's breach of an applicable federal regulation may serve as evidence of negligence. *See*, *e.g.*, *Robertson v. Burlington N. R. Co.*, 32 F.3d 408, 410 (9th Cir. 1994).

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²³ Even if the TCA and PMTA were relevant to the *Daubert* analysis, which they are not, JLI mischaracterizes what information would be relevant in that context. Specifically, JLI contends that combustible cigarettes and other ENDS devices are the only appropriate comparisons for JUUL products—not, for example, nicotine cessation or replacement therapy products. JLI is wrong. It selectively cites the Premarket Tobacco Product Applications and Recordkeeping Requirements ("PTPA") to suggest that the FDA recommends that applicants compare health risks of ENDS products to cigarettes and other similar ENDS products. (JLI Mot. 2 at 2-3). But the PTPA also

B. Experts Regularly Opine on Addiction Without Conducting a Full and Formal Abuse Liability Assessment.

JLI also contends that the only proper method of assessing the addictiveness of JUUL products is a formal ALA, and that anything else is *per se* irrelevant and unreliable. (JLI Mot. 2 at 3-5).²⁴ Again, JLI is wrong. Though the ALA is applied throughout the tobacco and pharmaceutical industries, JLI has not cited any case establishing that the only methodology for determining addiction is to conduct a full and formal ALA. Conversely, numerous cases show that experts routinely assess addiction generally and nicotine addiction specifically, without conducting a

For example, in *Kerrivan v. R.J. Reynolds Tobacco Co.*, No. 309CV13703WGYHTS, 2014 WL 12623812 (M.D. Fla. Sept. 30, 2014), the court held that Dr. Neil Grunberg, one of Plaintiffs' experts in this case, was qualified to testify about the minimum effective dose of nicotine necessary to initiate and sustain addiction because of his education, professional qualifications, and work history. *Id.* at *2. The *Kerrivan* court noted that "Dr. Grunberg wrote his doctoral dissertation on the effects of nicotine on the brain, and then, as the Scientific Editor of the 1988 Surgeon General's Report on Nicotine Addiction, he spent years studying and compiling research to determine why people smoke." *Id.* The defendants' objections about Dr. Grunberg's methodology and reliability went to the weight, not the admissibility, of the evidence. *Id. See also Bifolck v. Philip Morris, Inc.*, No. 3:06-CV-1768 (SRU), 2017 WL 4232955 at *1-*2 (D. Conn. Sept. 25, 2017) (holding that one expert was qualified to testify about the minimum nicotine threshold for addictiveness, and that Dr. Grunberg was qualified to testify "(1) that there is a minimum effective dose range of nicotine

formal ALA.

²⁴ "Abuse liability" is "interchangeable" with the term "abuse potential." i.e..

Pltf. Ex. 15, Henningfield Dep. (Class) at

28 64:11-25; 65:16-21, Sep. 23, 2021.

requires consideration "of the risks and benefits of permitting the marketing of the new tobacco product to the population as a whole, including users and nonusers of tobacco products." The FDA review also includes health risks—including initiation, switching, polytobacco product use, and cessation—that may occur due to a new tobacco product. PTPA, 86 Fed. Reg. 55300, 55359. While the FDA declined to require comparisons to all other products in every application, it acknowledged that the appropriate comparison products might vary. *Id.* at 55359-60. Of course, none of these standards govern the admissibility of expert opinion.

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necessary to initiate and sustain addiction, (2) about medical and public health history regarding
cigarettes and nicotine addictiveness data, and (3) that [Philip Morris] has manipulated cigarette
design to foster addiction among smokers."); Pooshs v. Phillip Morris USA, Inc., 287 F.R.D. 543,
552-53 (N.D. Cal. 2012) (plaintiff's expert "qualified by education, experience and training to
testify about nicotine addiction and methods of assessing it," despite the defendant's argument that
the expert did not rely on peer-reviewed or generally accepted methods to diagnose addiction);
Burton v. R.J. Reynolds Tobacco Co., 183 F. Supp. 2d 1308, 1311-12 (D. Kan. 2002) ("The Court
is persuaded that Dr. Burns is qualified by his knowledge, experience and education to testify about
the health consequences of smoking, including the harmful and addictive effects of nicotine.
Testimony that a cigarette not containing nicotine, if one were designed and manufactured, would
be healthier than a cigarette containing nicotine goes to the subject on which Dr. Burns is qualified
to testify, the harmful effects of nicotine."). None of these cases cited PMTA/TCA standards as the
relevant framework for such testimony, and none required a showing that the expert had conducted
a full and formal ALA as a prerequisite for testifying.

Pltf. Ex. 16, Henningfield Dep. at 69:19-

70:16, Jan. 13, 2022. In fact, Dr. Henningfield, has opined on addictiveness without performing an ALA. In *Schwab v. Philip Morris USA, Inc.*, 449 F. Supp. 2d 992 (E.D.N.Y. 2006), *rev'd sub nom. on other grounds McLaughlin v. Am. Tobacco Co.*, 522 F.3d 215 (2d Cir. 2008), the court permitted Dr. Henningfield to testify that light cigarettes would sustain addiction and deliver tar and nicotine equivalent to traditional cigarettes while appearing to be safer—without having conducted an ALA.

Id. at 1228.

Pltf. Ex. 16,

Henningfield Dep. at 69:3-70:6, Jan. 13, 2022.

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at 69:19-70:6.²⁵

Regardless, in forming their opinions, Plaintiffs' experts conducted analyses that JLI acknowledges are part of a formal ALA—*e.g.*, pharmacokinetic studies, toxicant emissions, biomarkers of exposure, and user behaviors (both for JUUL standing alone and as compared to cigarettes, nicotine replacement therapies ("NRTs"), and other nicotine delivery systems). *See*, *e.g.*, JLI Ex. 23, Shihadeh Rpt. at 14-49 (§ 4); JLI Ex. 18, Prochaska Rpt. at 36-61 (§§ 6-9). In addition, Plaintiffs' experts base their addictiveness opinions on their collective decades of education and experience in the field of nicotine and addiction, including their own peer-reviewed and published research they conducted using reliable, recognized methodologies, as well as JLI's own internal testing. *See*, *e.g.*, JLI Ex. 23, Shihadeh Rpt. at 2-4, 14-49 (§ 4); JLI Ex. 18, Prochaska Rpt. at 1-2, 36-48 (§ 6). JLI is free to argue that the research conducted by Plaintiffs' experts "is less substantial than what [JLI] itself carrie[d] out," but it cannot overcome that Plaintiffs' experts relied on JLI's own testing. Whether one type of testing is better than another "is for cross-examination." *Maldonado*, 2021 WL 1947512 at *15. Any "countervailing evidence [JLI's] experts introduce ... is a matter for the jury to weigh." *Id*.²⁶

C. Plaintiffs' Experts' Opinions on the Addictiveness of JUUL are Relevant.

Expert opinion is relevant where it will "assist the trier of fact to understand or determine a fact in issue." *Fujifilm Corp. v. Motorola Mobility LLC*, No. 12-cv-03587-WHO, 2015 WL 1737951 at *1 (N.D. Cal. Apr. 8, 2015) (quoting *Cooper v. Brown*, 510 F.3d 870, 942 (9th Cir. 2007)). Opinions regarding the addictiveness of JUUL—including its nicotine delivery

²⁶ Carter (2009), which was co-authored by JLI expert witness Dr. Henningfield, acknowledges

²⁵ Similarly, in another case in which he determined that the plaintiff was "highly addicted to tobacco," Dr. Henningfield explained that the plaintiff's addiction was "pretty obvious based on what I saw," and admitted that he had not gone through any defined set of factors or industry tests because "[t]here isn't a specific test that I need as an expert." Pltf. Ex. 12, Henningfield Dep. in *Goveia v. R.J. Reynolds Tobacco Co.*, No. 2008-CA-000760-O (Orange Co. Fla. Cir. Ct.) at 59:17-61:12, 62:6-64:21, Aug. 28, 2013. (emphasis added).

that ALA has its limitations. Pltf. Ex. 18, Carter et al. (2009) at 3243 (discussing several "factors" that can influence "actual abuse of a drug" but "are typically not examined in traditional ALA"). In the context of FDA consideration of new modified risk tobacco products, Carter (2009) notes that "ALA data" is just "one important type" of evidence relevant to the FDA's evaluation of a product's addictiveness. *Id.* at 3256.

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characteristics, product features, and other effects that are known to contribute to its abuse liability—address central issues in this MDL.

1. <u>JUUL Products' Addictive Qualities and Design Features are</u> Relevant.

JLI again argues that expert opinions regarding the addictiveness of JUUL products lack "fit" because they are not confined to an ALA under the four corners of the TCA or the PMTA process. But, as explained above, addiction experts have many tools for assessing the addictiveness or abuse liability of nicotine products. And, relevance is defined by the parties' claims and defenses, not the TCA. *See supra*, Section VI.A. Even a cursory review of Plaintiffs' claims demonstrates that the addictive qualities of JUUL products are highly relevant.²⁷

2. The Pharmacological Effects and Delivery Characteristics of Alternative Nicotine Concentrations are Relevant to Assessing JUUL Addictiveness.

JLI argues that comparisons of the addictiveness of JUUL products with nicotine cessation products are irrelevant. (JLI Mot. 2 at 6-11). This argument is again based on the false premise that the TCA sets the standard. As discussed above, it does not. JLI suggests that, under the PMTA or TCA regulatory framework, JUUL products may be compared only to combustible cigarettes or

²⁷ Plaintiffs allege that Defendants designed, marketed, and sold a "highly addictive product." (First MTD Order at 6); Tucson Unified School District v. JUUL Labs, Inc. et al., No. 3:19-cv-07335-WHO (N.D. Cal.), ECF No. 28 (Second Amended Complaint) ("Tucson Unified SAC") at ¶ 60 (defendants "create[ed] [a] highly addictive product" to achieve their "shared goal of growing a youth market")). Plaintiffs allege that Defendants created or contributed to a youth e-cigarette epidemic, in part, by designing a product with unparalleled nicotine delivery coupled with "lower throat harshness and discomfort than prior tobacco or existing ENDS products." (First MTD Order at 6; Tucson Unified SAC at 37 ("JLI and Bowen Made Highly Addictive E-Cigarettes Easy for Young People and Non-Smokers to Inhale")). These product features, and others, facilitated initiation to vaping and increased nicotine use by current cigarette and e-cigarette users. (ECF No. 1135 (Second Amended Consolidated Class Action Complaint) ("SACCAC") at ¶ 4 ("JLI and Bowen designed JUUL products to create and sustain addiction, not break it.")). Plaintiffs allege further that JUUL products' sleek design and flavors contributed to the addictiveness of JUUL products. (Tucson Unified SAC at ¶ 72 ("JLI marketed that highly-addictive device as healthy, safe, cool and available in kid-friendly flavors."); SACCAC at ¶ 6 (JLI offered kid-friendly flavors ... because Defendants knew that flavors get young people hooked.")). So, too, did JUUL products' lack of any features to discourage continuous and excessive use, such as a lockout feature or doselimiting feature. These product features, and their impact on JUUL users, are at the heart of Plaintiffs' claims. Defendants' contention that expert opinion regarding the addictiveness or abuse liability of JUUL products do not "fit" (JLI Mot. 2 at 5-12) is, thus, without merit.

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other e-cigarettes. (*See id.*). However, no such limitation exists. *See supra*, Section VI.A, n.2. Because the addictiveness of JUUL products is highly relevant, expert opinions comparing JUUL's features and nicotine delivery with other nicotine products—such as NRTs—will assist the jury.

Plaintiffs' experts extensively analyzed JUUL's product features and nicotine delivery characteristics and assessed whether these features contributed to the addictive propensity of the product. *See*, *e.g.*, JLI Ex. 8, Grunberg Rpt. at 33-60 (§ III); JLI Ex. 6, Eissenberg Rpt. at 49-60 (§ iii), JLI Ex. 23, Shihadeh Rpt. at 14-49 (§ 4); JLI Ex. 18, Prochaska Rpt. at 36-48 (§ 6). In doing so, the experts noted how some of these features and device performance compared to other nicotine products, including NRTs, combustible cigarettes, and other e-cigarettes. *See id*. ²⁸ These analyses inform the broader issue: the addictiveness of JUUL products.

. See generally Pltf. Ex. 13, Henningfield Rpt., Aug. 27, 2021.; see also Pltf. Ex. 14, Henningfield Rpt. at 2, Nov. 20, 2021

²⁹ There is no basis to prevent

Plaintiffs' experts from comparing JUUL products with NRTs.

Tacitly admitting relevance, JLI attempts to refute Plaintiffs' experts' opinions "that lower nicotine can effectively switch smokers away from combustible cigarettes." (JLI Mot. 2 at 8). First, disagreements about the science are points for cross-examination that do not impact admissibility. See Scripps Health v. nThrive Revenue Sys., LLC, No. 19-CV-00760-H-DEB, 2021 WL 3372835 at *7 (S.D. Cal. May 10, 2021) (stating that "disagreement with an expert's opinion is not a basis for exclusion"). Second, it is JLI, not Plaintiffs, that argues that JUUL was designed and sold as a

²⁸ Plaintiffs' experts do not, contrary to JLI's suggestion (JLI Mot. 2 at 7), "opine that JUUL products should have been cessation devices" or "assume that cessation is the standard" (JLI Roadmap at 26); instead, it is one of many relevant and important comparisons made.

²⁹ As noted in his November 20 Report, Dr. Henningfield offers many of the same comparisons and conclusions in JLI's abuse liability assessment included with JLI's PMTA. (*Id.* at 3).

1	switching products. Plaintiffs' experts' offer opinions on the addictiveness of JUUL generally, not
2	merely as switching or cessation products. The admissibility of their opinions does not turn on
3	whether JUUL is a successful switching product, and even if that were so, JLI has not shown that
4	to be the case.
5	Similarly, JLI's arguments about JUUL nicotine strength lack merit. JLI argues that its 5%
6	JUULpods were necessary to user satisfaction; that the 5% JUUL pods present no more abuse
7	liability than lower nicotine strengths; and that lower nicotine levels, such as the 3% and 1.7%
8	levels, do not effectively switch combustible cigarette users. But JLI has never justified the 5%
9	nicotine content of its JUUL products, whether as a switching device or otherwise.
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11	As Dr. Shihadeh explains,
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14	. JLI Ex. 23, Shihadeh Rpt. at 18.30
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17	" JLI Ex. 23, Shihadeh Rpt. at 35.31 Indeed, millions of smokers have quit
18	smoking with no nicotine at all, or with the assistance of NRTs that have lower and slower nicotine
19	deliveries, lower PK profiles, and lower abuse liability than the 5% formula that JLI marketed and
20	sold to the general public. ³²
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22	³⁰ See also JLI Ex. 18. Prochaska Rpt. at 55-59; JLI Ex. 6. Eissenberg Rpt. at 74-80, 98-99 (
23).
24	³¹ See also JLI Ex. 6. Eissenberg Rpt. at 75 (Pltf. Ex. 17.
25	Xing Dep. at 151:13-153:4 (
26	³² It is widely recognized, including by JLI's expert witness Dr. Henningfield, that
27	Pltf. Ex.14. Henningfield Rpt. at 15, Nov. 20, 2021 (
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Advancing arguments that go to the weight of evidence, not to admissibility, JLI points to two studies, arguing that they support its claim that "lower nicotine products are not sufficiently satisfying" to lead adult cigarette smokers to switch. (JLI Mot. 2 at 9-10). This issue is best left for cross examination. Moreover, JLI's reliance on these articles is misplaced.

First, JLI points to a 2017 paper co-authored by Drs. Shihadeh and Eissenberg, among others, as justifying the 5% nicotine formulation of JUUL as necessary or demonstrating that lower nicotine concentrations cannot deliver a satisfying user experience. But the products at issue in the 2017 paper were highly aversive—i.e., difficult to use—freebase nicotine products, unlike JUUL products. Moreover, even if lowering the nicotine content might create a less effective switching product, that does not mean that 5% nicotine by weight is appropriate or necessary. JUUL's 5% product "had the highest concentration of nicotine available on the market" JLI Ex. 23, Shihadeh Rpt. at 15, yet the nicotine was manipulated such that it was delivered with far less harshness than existing products that delivered far less nicotine.

JLI next discusses a 2021 paper co-authored by Dr. Eissenberg that studied various nicotine concentration levels' relationship to cigarette abstinence. (JLI Mot. 2 at 10). JLI contends that the study shows that lower nicotine concentration levels reduce switching effectiveness. (See id.). Again, this is not the question at issue in this litigation. But even if JLI's contention were both relevant and accurate, that fact would not justify the 5% nicotine concentration with unparalleled palatability that JUUL marketed and sold to the public, and particularly to young non-smokers.

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id. at 16 (

(internal citation omitted);

Statement by Jack E. Henningfield, Ph.D. Before the Committee on Labor and Human Resources U.S. Senate, Feb. 24, 1998 at 4, available at https://www.industrydocuments.ucsf.edu/docs/ #id=if110029 (acknowledging the impact of NRTs on smoking cessation). But, unlike e-cigarettes, there is no crisis of youth use of those products.

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Indeed, in the 2021 study, the authors successfully switched 14 of 130 (10.8%) study participants from combustible cigarettes to ENDS using a lower nicotine formulation at 36 mg/ml.^{33,34}

The final two studies cited by JLI fare no better in justifying JUUL's 5% nicotine formulation. (JLI Mot. 2 at 10-11). First, JLI funded these studies, both of which were authored by Goldenson et al. in 2021. JLI Ex. 18, Prochaska Rpt. at 47. Setting aside the issue of bias, which is for the jury, both studies contain significant methodological flaws. For instance, the first Goldenson study cited by JLI compared switching rates between smokers in the United Kingdom and the United States, but it ignored the societal costs of the teen vaping epidemic in the United States, which has not occurred in the United Kingdom.³⁵ In the second JLI-funded study,³⁶ Goldenson et al. tested various nicotine concentrations in products with different physical properties—e.g., a cotton versus silica wick. These differences impacted the results, and once those distinctions were

³³ This switching rate using a lower nicotine formulation exceeds overall rates of smokers trying to quit, according to a recent study. *See* U.S. Dept. of Health and Human Services, *Smoking Cessation:* A Report of the Surgeon General (2020) at 495, available at https://www.cdc.gov/tobacco/data_statistics/sgr/2020-smoking-cessation/index.html ("less than 10% of smokers who try to quit succeed in quitting for 6 months or longer").

³⁴ By contrast, JUUL products contain 160% as much nicotine delivered in a manner that, through nicotine manipulation, makes JUUL products much less aversive—i.e., easier to inhale and more kid-friendly, than the 36 mg/ml products studied. Further, JUUL products have not been proven as effective switching products. *See* JLI Ex. 6, Eissenberg Rpt. at 63 (despite a stated mission of switching cigarette smokers, JLI "conducted no randomized control trials with objective verification of cigarette smoking to examine if the [JUUL] product served" that mission):

); JLI Ex. 18, Prochaska Rpt. at 5 ("Despite failure to demonstrate that JUUL reduces exposure to hazardous or potentially hazardous compounds, poses less risk than cigarettes, or aids in quitting smoking, JUUL has been advertised as a switching device"); id. at 59

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³⁵ Pltf. Ex. 21, Nicholas I. Goldenson et al., Differences in Switching Away from Smoking Among Adult Smokers Using JUUL Products in Regions with Different Maximum Nicotine Concentrations: North America and the United Kingdom, *Nicotine & Tobacco Rsch. at 1821* (2021).

³⁶ Pltf. Ex. 20, Nicholas I. Goldenson et al., An Open-Label, Randomised, Controlled, Crossover Study to Assess Nicotine Pharmacokinetics and Subjective Effects of the JUUL System with Three Nicotine Concentrations Relative to Combustible Cigarettes in Adult Smokers, *23 Nicotine & Tobacco Research* at 947 (2021).

eliminated, lower nicotine concentrations proved similar to higher concentrations in terms of user "satisfaction."³⁷

Regardless, the jury will not determine whether JUUL 1.7% pods, or other nicotine formulations, could effectively switch combustible cigarette smokers. The questions will focus on the reasonableness of JLI's acts and omissions, and whether its product is defective. The very fact that JLI's Motion veers into the fine details of scientific studies reveals how unmoored its arguments are from a proper *Daubert* challenge. JLI does not argue these points to challenge Plaintiffs' experts' qualifications or methodologies. Rather, JLI suggests they should be excluded because, in JLI's estimation, their opinions are wrong. But the *Daubert* inquiry focuses on experts' methodologies, not their conclusions. *Daubert*, 509 U.S. at 595. Because the experts' opinions are based on extensive facts and data, and reliable methodologies applied by qualified experts in the field, they are admissible. *See* Fed. R. Evid. 702. JLI's disagreements on the science and resulting abuse liability determinations should be left for cross-examination.

3. The Addictiveness of JUUL Products to Youth is a Central Issue in This Litigation and Thus, Expert Opinions on This Issue are Relevant.

Next, JLI broadly asserts that "expert opinions that JUUL products are too addictive for youth" are not relevant. (JLI Mot. 2 at 11-13). JLI's position is untenable and remarkable, given Plaintiffs' numerous allegations regarding the appeal of JUUL products to youth, the mental and physical health impacts of JUUL products on youth, and the susceptibility of youth to nicotine addiction.³⁸ It follows that expert opinions regarding the appeal and impact of JUUL products to youth "fit" the case.

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³⁷ Indeed, based on the results from other studies, Project Bears and Project Cubs, which were funded by JLI but that JLI chose not to publish, JLI concluded that "[s]mokers recognize differences between the strengths in flavor, throat hit and nicotine hit. Yet, there is little difference in satisfaction or purchase interest by strength across the targets." JLI Ex. 6, Eissenberg Rpt. at 79; see also JLI Ex. 18, Prochaska Rpt. at 58-59.

³⁸ First MTD Order at 6 (defendants sought to "vastly expand the [nicotine] market by capturing and addicting individuals – **specifically including youth users** – who had not previously used tobacco or ENDS products") (emphasis added); ECF No. 1694 ("Second MTD Order") at 5 ("Plaintiffs provide more detail in their allegations regarding Monsees and Bowen's roles in creating, testing, and then misrepresenting the addictiveness and nicotine levels delivered by the

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Perhaps recognizing the folly of its argument, JLI seeks exclusion of only two sets of opinions. First, it targets Dr. Grunberg's opinions regarding "Youth Abuse Liability." (JLI Mot. 2 at 11). In support of this argument, JLI curiously asserts that "all products containing nicotine are too addictive for youth." (Id.). While Plaintiffs do not disagree, JLI again misses the point: Plaintiffs allege that JLI designed, marketed, and sold a uniquely appealing and addictive product to youth and young adults. A contested issue in this MDL will be whether JLI incorporated product design elements, including a nicotine delivery profile, that were uniquely appealing and addictive for youth. This issue makes expert opinion regarding the addictiveness of JUUL products to youth more relevant, not less.³⁹

Second, JLI seeks to exclude certain opinions of Drs. Prochaska, Shihadeh, and Eissenberg concerning the role of flavors in youth addiction. (JLI Mot. 2 at 12) As literature cited by JLI and relied upon by its experts makes clear, an assessment of addictiveness or abuse liability is not limited to nicotine delivery. Pltf. Ex. 18, Carter (2009) at 3242-43. Rather, "non pharmacological factors ... take on even greater importance as determinants of use and addiction to tobacco products." JLI Ex. 23, Shihadeh Rpt. at 14 (quoting FDA 2012 MRTP Guidance). Plaintiffs' allegations regarding JLI's targeting of youth are central to this MDL, with flavors playing a prominent role in those allegations.

In a desperate attempt to cast doubt on the role of flavors in creating and sustaining nicotine addition, JLI contends that flavors are necessary to help adult smokers switch and "may also appeal

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JUUL product with the **specific aim of targeting youth**.") (emphasis added); Tucson Unified SAC at ¶¶ 5-6 (JUUL's "nicotine formulas and delivery methods," including being smooth and easy to inhale, product design, and "kid-friendly flavors" were "designed for youth") (emphasis added), p. 37 ("JLI and Bowen Made Highly Addictive E-Cigarettes Easy for Young People and Non-Smokers to Inhale") (emphasis added)).

³⁹ JLI states that youth prevention was a "purpose of the [TCA]" in light of public concern in that regard, and that "efforts to curb youth use have been applauded for decades." (JLI Mot. 2 at 11). Aside from providing no support for JLI's argument to exclude youth addictiveness opinions, this statement ignores that the tobacco industry's "youth prevention" efforts have been widely recognized as counterproductive ploys to expand tobacco's reach and appeal. U.S. Dept. of Health and Human Services, Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General, Ch. 5 (2012), available at https://www.ncbi.nlm.nih.gov/books/NBK99237 /pdf/Bookshelf_NBK99237.pdf (last visited Jan. 27, 2022). Plaintiffs allege that JLI's "youth prevention" programs were a sham in the footsteps of big tobacco. (See, e.g., Tucson SAC, ¶ 486-92).

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to youth." (JLI Mot. 2 at 12 (emphasis added)) Even if that were true, it would not render irrelevant expert opinions about the role of flavors.

Pltf. Ex. 16, Henningfield

Dep. at 130:7-12, Jan. 13, 2022

Thus, even if flavors help adults to switch, that fact does not exonerate JLI from all liability for their youth appeal and, certainly, it does not render expert testimony on the topic irrelevant or inadmissible. JLI's disputing the intent of its decision to market JUUL products in kid-friendly flavors renders expert opinion on that issue more relevant, not less. 40

Plaintiffs' experts' opinions regarding the addictiveness of JUUL products to youth and young adults are relevant, reliable, and admissible.

D. Expert opinion regarding JUUL's addictiveness relative to cigarettes is relevant and reliable, and JLI's disagreements go to weight, not to admissibility.

JLI does not generally challenge the "fit" of Plaintiffs' experts' opinions regarding JUUL products' abuse liability relative to combustible cigarettes.⁴¹ Nor could it. As discussed above, expert opinion regarding the JUUL products' design, including nicotine delivery and non-pharmacological effects, relative to other nicotine products will inform a central issue in this MDL:

PLAINTIFFS' OMNIBUS OPPOSITION TO DEFENDANTS' DAUBERT MOTIONS CASE NO. 19-MD-02913-WHO

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⁴⁰ The appeal of flavors to youth is well established. *See* JLI Ex. 23, Shihadeh Rpt. at 53 (citing Leventhal et al., JAMA (2019)); Pltf. Ex. 19, Cullen KA et al., *e-Cigarette Use Among Youth in the United States*, 2019, JAMA 2019:322 (21:2095-2103) (72.2% of high school students and 59.2% of middle school students who were exclusive e-cigarette users reported current use of flavored e-cigarettes); U.S. Dept. of Health and Human Services, *E-Cigarette Use Among Youth and Young Adults: A Report of the Surgeon General*, Ch. 2 (2016), https://www.cdc.gov/tobacco/data_statistics/sgr/e-cigarettes/index.htm (last visited Jan. 27, 2022) ("among youth who have ever tried an e-cigarette, a majority used a flavored product the first time they tried an e-cigarette"); JLI Ex. 18, Prochaska Rpt. at 59-60 ("Adolescents report flavors are primary reasons for use, and the majority of youth e-cigarette ever users initiated e-cigarette use with a non-tobacco flavored product.") (citing studies in support); *see also* Pltf. Ex. 18, Carter et al. (2009) at 3242 ("Flavorants such as cocoa, licorice, fruit extracts, or menthol have been suggested to increase the attractiveness of tobacco products and might be particularly appealing to youth.")). Dr. Shihadeh concluded that "JUUL had no countervailing evidence that flavors were a 'necessary evil' that had to be tolerated" to effectively switch adult smokers. JLI Ex. 23, Shihadeh Rpt. at 53.

⁴¹ JLI does argue that opinions regarding product misuse—"pod popping"—do not fit. (JLI Mot. 2 at 14-15). As discussed below, Plaintiffs' experts' opinions regarding this frequent practice by JUUL users, which resulted in nicotine delivery spikes, are relevant and reliable.

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the addictiveness of JUUL products. Instead, JLI argues that Plaintiffs' experts' opinions regarding JUUL products relative to combustible cigarettes are unreliable because "the scientific data show the opposite." (JLI Mot. 2 at 13). But that is nothing more than yet another disagreement among experts. "This is a battle of the experts and goes to weight. ... Each can make their case to the jury." Maldonado, 2021 WL 1947512 at *16; Dorn v. Burlington N. Santa Fe R.R. Co., 397 F.3d 1183, 1196 (9th Cir. 2005) ("[B]attle of expert witnesses is properly reposed in the jury") (quotations omitted). JLI's challenges to Plaintiffs' experts' opinions regarding JUUL's product design relative to combustible cigarettes are without merit.

First, JLI contends that Drs. Shihadeh and Prochaska have not shown that JUUL products have a higher "nicotine absorption" or are "more addicting than combustible cigarettes." (JLI Mot. 2 at 13-14). As discussed, the jury will not decide whether JUUL is more addictive than a cigarette. JLI may be found negligent—and JUUL may be found defective—regardless of whether the product is more or less addictive than a cigarette. JLI is free to argue to a jury that JUUL products are no more dependence-producing than one of the most addictive consumer products ever invented. JLI's attempt to reframe the issue in hopes of labeling some of Plaintiffs' experts' opinions unreliable is, therefore, misguided. Regardless, JLI's factual arguments are off base.

For instance, JLI argues that the science shows "the PK data for JUUL products is comparable to that of combustible cigarettes." (JLI Mot. 2 at 13). Even if that were the relevant question, JLI provides no support for its argument. Rather, JLI relies on deposition testimony of Drs. Shihadeh and Prochaska. 42 (JLI Mot. 2 at 13). But as Plaintiffs' experts have shown, for some users JUUL products deliver more nicotine than combustible cigarettes. JLI Ex. 6, Eissenberg Rpt.

⁴² While Dr. Shihadeh agreed he was not aware on the day of his deposition of a published study showing that "Juul's Cmax is statistically significantly higher than combustible cigarettes" (JLI Ex. 52, Shihadeh Dep. at 258:12-17), there are many other factors demonstrating the highly addictive nicotine delivery characteristics of JUUL products. See, e.g., JLI Ex. 23, Shihadeh Rpt. at 57 ("A confluence of JUUL design attributes facilitate high levels of use and addiction."). And, as Dr. Prochaska pointed out, the two studies she was asked about on this point have their limitations, such as small sample sizes with a lab setting that necessarily differs from real-world use. JLI Ex. 47, Prochaska Dep. at 129:24-131:16; 162:16-163:1. And in the second study, the Cmax values are similar only if one uses a mean value rather than median. The median values showed "that, for the most part, people on average were getting ... half the Cmax value on cigarettes compared to Juul." Id. at 175:18-176:6. Mean values were comparable likely as a result of outlier user data pulling the value up. *Id*.

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	JLI Ex. 18, 1	Prochaska Rpt. at 46
ndeed, JLI's Phase 0 study		
	<i>See Id.</i> at 40	
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Eissenberg Rpt. at §3.E.		

JLI's reliance on Shiffman (2021) does not help its cause. (JLI Mot. 2 at 13-14). JLI funded Shiffman (2021), and JLI paid to publish it in a pay-for-play journal, the American Journal of Health Behavior (AJHB). In fact, JLI bought a special issue devoted to studies that JLI funded, and the payments made by JLI to AJHB represented 84% of the journal's revenues for 2021. JLI Ex. 18, Prochaska Rpt. at 47. Shiffman also served as guest editor for the JUUL specific issue despite providing exclusive consulting services to JLI for research in support of JUUL's PMTA. *Id.* On bias alone, this study cannot credibly support the argument that Plaintiffs' experts' opinions are unreliable.

Further, JLI's suggestion that Dr. Shihadeh "admitted that he was not aware" of any studies contrary to Shiffman (2021) is misleading. (JLI Mot. 2 at 13). After stating he was familiar with the study and that he had cited works on the topic of dependence in his report, Dr. Shihadeh stated he would need to review Shiffman (2021) to ascertain whether he was aware of contrary studies. Pressed by counsel for JLI, and without re-reviewing the Shiffman study, Dr. Shihadeh stated he was "not aware of studies contrary or in support of" the findings in Shiffman (2021). JLI Ex. 52,

Shihadeh Dep. at 286:18-290:12. Regardless of whether Dr. Shihadeh was aware, top-of-mind, of contrary studies, he has opined that the study itself is unreliable. As explained in his report, "Shiffman et al. (2021) is an unreliable study whose design is biased to show that when smokers switch, they become less dependent. In reality, what this study shows is that when smokers switch, it becomes easier to obtain more nicotine." JLI Ex. 23, Shihadeh Rpt. at 47. Independent studies found that "40% of adult JUUL users are moderately or highly dependent on JUUL" and "40% of current JUUL users have made at least one quit attempt." *Id.* at 46 (citing Yings (2021), Dobbs (2021), Newcomb (2021), and Pulvers (2021)).

Id. at 47.

Next, JLI incorrectly asserts that Plaintiffs' experts' opinions regarding increased nicotine delivery from manipulating JUUL pods—

43—are irrelevant and unreliable. (JLI Mot. 2 at 14-15) JLI's argument again relies on an incorrect premise: that relevance in this MDL is defined by the TCA. Stacking false premise on false premise, JLI contends the TCA only considers comparisons to combustible cigarettes and other ENDS products relevant and, thus, no other data is relevant here. *See Id*.

As discussed, JUUL's nicotine delivery characteristics, including product design features

that affect nicotine delivery, are relevant to Plaintiffs' claims. That includes "pod-popping." As explained in Plaintiffs' experts' reports, pod popping—

44—"rewards the user with a high nicotine pulse" and "very likely increases the strength of the reinforcement and the abuse liability of JUUL." JLI Ex. 23, Shihadeh Rpt. at 28-30; JLI Ex. 18, Prochaska Rpt. at 4 (pod popping creates "a variable reinforcement schedule that with addiction is the hardest type of reinforcement to extinguish"); JLI Ex. 6, Eissenberg Rpt. at 139 ("Substantial (and at times erratic) increases in nicotine delivery increases JUUL's abuse liability/addiction potential."). JLI contends that Plaintiffs' experts' have not shown

⁴³ JLI Ex. 23, Shihadeh Rpt. at 29.

⁴⁴ And by Bellwether plaintiff, B.B. *See* JLI Ex. 19, Prochaska Rpt. (B.B.) at 7, 12, 20; JLI Ex. 26, Winickoff Rpt. (B.B.) at 2.

it compares to other ENDS products. (JLI Mot. 2 at 14-15). That is not the standard of relevance and comes nowhere close to challenging the reliability of Plaintiffs' experts' opinions regarding the increased addictiveness of JUUL products due to product manipulation. JLI's comparison to the VUSE Alto ENDS device—based on yet another JLI study—misses the point. (*Id.* at 15). The relevant issue is whether JUUL products were defective or JLI's conduct was unreasonable, not whether JUUL products were more or less defective than other ENDS products. In any event, JLI's comparison to the VUSE Alto is an apples-to-oranges comparison. VUSE Alto has a higher freebase fraction than JUUL and, thus, it is harsher to use and not likely to be used as frequently or as heavily.⁴⁵

Relatedly, JLI argues that the opinions of Drs. Prochaska and Shihadeh regarding the

that the resulting nicotine absorption is greater than that of combustible cigarettes, or analyzed how

Relatedly, JLI argues that the opinions of Drs. Prochaska and Shihadeh regarding the variable nicotine delivery of JUUL products resulting from pod-popping are unreliable. (JLI Mot. 2 at 16-17). JLI does not argue that variable reinforcement is irrelevant to the issue of addiction. Rather, JLI's entire argument on this point is that slot machines are an "inapt" analogy to the variable nicotine delivery of JUUL products. (*Id.* at 16). Whether they are or not, the notion of variable reinforcement, or variable ratio schedules, is a recognized scientific methodology for assessing addiction, as JLI admits. (*Id.*); *see also* JLI Ex. 52, Shihadeh Dep. at 129:14-17 ("There's a long literature on variable reward systems where the abuse liability is ramped up heavily when you have a variable reward."). And, while JLI suggests that JUUL products do not provide variable reinforcement, the nicotine spike resulting from product manipulation (or pod-popping) varies in magnitude and duration. JLI Ex. 23, Shihadeh Rpt. at 22-27. That is precisely the type of varied reinforcement that has been found to increase a product's addictiveness. Drs. Shihadeh's and

⁴⁵ See JLI Ex. 23, Shihadeh Rpt. at 18 ("while Vuse marketed a product with a 4.8% nicotine concentration, its 30% freebase nicotine fraction results in an order of magnitude greater vapor phase nicotine concentration than the JUUL aerosol, meaning that ... the Vuse is far more aversive to the user"); JLI Ex. 18, Prochaska Rpt. at 40 ("Nicotine in free base (unprotonated) form ... is harsh to inhale. ... Irritation with inhalation is a deterrent to smoking among nicotine-naïve individuals, including adolescents."); JLI Ex. 6, Eissenberg Rpt. at 64 ("aerosol containing a high concentration of freebase nicotine is inherently irritating to the human throat"); Pltf. Ex. 11, Myers Dep. at 152:8-11 ("most of the throat hit, which is observed often as harshness, is drive predominantly by that freebase nicotine").

Prochaska's opinions—that pod-popping results in spikes in nicotine delivery—apply a recognized methodology to the facts and data of this case and, therefore, are relevant and reliable.

E. **Conclusion**

For all the foregoing reasons, JLI's Motion to exclude Plaintiffs' experts' opinion on the issue of JUUL products' addictiveness and abuse liability should be denied.

VII. **JLI MOTION #3: TOXICITY**

JLI seeks to exclude opinions regarding general and specific causation. The question before this Court is not whether the Plaintiff's experts are correct or even what conclusion the Court would come to if it were the trier of fact. The sole question is whether each challenged expert used a reliable methodology. *Primiano*, 598 F.3d at 565. JLI's motion nevertheless attempts to convince the Court that it is "right" on all issues as opposed to making a serious, specific methodological challenge to the Plaintiff's experts. JLI's motion should be denied because Plaintiffs have produced evidence from qualified experts who have applied a reliable methodology to answer the question of whether JUUL is capable of causing the harms alleged generally and those sustained by B.B.

With respect to qualifications, there is no question that Plaintiffs general and specific causation experts are nationally and internationally recognized experts in the fields. With respect to methodology, each expert followed a rigorous and accepted methodology in assessing and weighing the scientific evidence on causation in the same manner that they and their peers use in their professional work outside of litigation. These methods include employing the causation framework and considerations described by Sir Bradford Hill in his seminal 1965 address and the principles of evidence-based medicine. ("Hill Principles"). 46 At best, JLI's challenges raise nothing more than jury-appropriate questions because at the core of their argument is the difference in the interpretation of the scientific evidence. Accordingly, JLI's motion must fail.

Plaintiffs turn first to JLI's misstatement of the law on pages 2-7 of its motion.

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⁴⁶ Austin Bradford Hill, *The Environment and Disease: Association or Causation?*, 58 Proc. Royal Soc'y Med. 295 (1965).

A. <u>Daubert Law is Well-Established on Causation and JLI's Recitation of That Law Misses the Mark</u>

The Ninth Circuit recognizes that "causation need not be established to a high degree of certainty for expert testimony to be admissible under Rule 702." *Kennedy v. Collagen Corp.*, 161 F.3d 1226, 1230 (9th Cir. 1998). Put another way, "[c]ausation can be proved even when we don't know precisely *how* the damage occurred if there is sufficiently compelling proof that the agent must have caused the damage *somehow*." *Id.* (citing *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d 1311, 1314 (9th Cir. 1995)). Because their causation testimony "is supported by scientific evidence and will assist the trier of fact, [it] is admissible under Rule 702," Plaintiffs experts' have satisfied their burden. *Kennedy v. Collagen Corp.*, at 1231 (holding that a district court erred in excluding expert testimony when it "failed to consider all of the reasoning or methodology" relied upon by the expert in rendering a causation opinion).

First, courts have applied this liberal approach "favoring admission," In re Roundup Prod. Liab. Litig., 390 F. Supp. 3d. 1102, 1112 (N.D. Ca. July 10, 2018), to their analyses of general causation opinions by "taking into account the broader picture of the experts' overall methodology" rather than "looking too narrowly at each individual consideration." Wendell v. GlaxoSmithKline LLC, 858 F.3d 1227, 1233 (9th Cir. 2017). Exclusion of expert testimony is only appropriate when such testimony qualifies as irrelevant or "junk science." Otherwise, the trial court should cede complex issues to the jury and rely on the traditional safeguards of the adversary system—active cross-examination, presentation of contrary and competing expert testimony—rather than exclude from juror scrutiny for fear that they will not grasp its complexities or satisfactorily weigh its inadequacies. Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579, 596, 113 S. Ct. 2786 (1993).

Second, differing and competing expert opinions, precisely what JLI has presented to the Court, are traditionally left for the jury. The *Daubert* analysis focuses on the methodology underlying an expert's opinion, not the expert's conclusions. *Daubert*, 509 U.S at 585; see also Beech Aircraft Corp. v. Rainey, 488 U.S. 153, 168 (1988); Fed. R. Evid. 702.

Third, causal inference is a matter of judgment about the totality of the scientific evidence. "Drawing causal inference . . . requires judgment and searching analysis based on biology, of why

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a factor or factors may be absent despite a causal relationship, and vice versa." *Reference Manual on Scientific Evidence* (3d ed. 2011) at 600. As noted in the *Reference Manual*: "Although the drawing of causal inference is informed by scientific expertise, it is not a determination that is made by using an algorithmic methodology." *Id.* As this judgment is a scientific determination, it can evolve "as new evidence develops" because "the scientific enterprise must always remain open to reassessing the validity of past judgments." *Id.* at 598. The judgment of whether to draw a causal inference can lead to disagreement amongst experts in the field. *See, e.g., Warren v. United States,* 2021 WL 1990644, *7 (D. Hawaii May 18, 2021) ("And, because medical knowledge is often uncertain, medical testimony need not be conclusive."). In the end, deciding whether associations are causal typically is not a matter of statistics alone, but also rests on scientific judgment. *Reference Manual on Scientific Evidence* at 20, 21, 222, 553, 565, 591, 599 and 600. JLI's briefing is silent on these essential points.⁴⁷

Fourth, a causal inference requires an examination of the totality of the scientific evidence. "Scientific inference typically requires consideration of numerous findings, which, when considered alone, may not individually prove the contention." *Id.* at 19–20; see also United States v. Sandoval-Mendoza, 472 F.3d 645, 655 (9th Cir. 2006). This is how science outside of the courtroom functions. There is simply no definitive check-list or magic formula for making scientific judgments. As explained in the Reference Manual:

It appears that many of the most well-respected and prestigious scientific bodies (such as the International Agency for Research on Cancer (IARC), the Institute of Medicine, the National Research Council, and the National Institute for Environmental Health Sciences) consider all the relevant available scientific evidence, taken as a whole, to determine which conclusion or hypothesis regarding a causal claim is best supported by the body of evidence. In applying the scientific method, scientists do not review each scientific study individually for whether by itself it reliably supports the causal claim being advocated or opposed.

Reference Manual on Scientific Evidence at 600 (underlying added).

⁴⁷ Reference Manual on Scientific Evidence, Federal Judicial Center, Third Edition (2011).

Fifth, science does not demand certainty. Nor does the law. Under Ninth Circuit Daubert standards, the trial court should not impose "a standard of scientific certainty . . . beyond that which Daubert envisions." Primiano, 598 F.3d at 565-66. Science and medicine often do not lead to certainty and the law does not require certainty. Id. Again, Fed. R. Evid. 702 has "a liberal policy of admissibility." In re Roundup Prod. Liab. Litig., 390 F. Supp. 3d. at 1112.

In *In re Roundup Prod. Liab. Litig.*, the court found that three experts "adequately demonstrated that [their] opinions regarding general causation [are] sufficiently 'within the range of accepted standards governing how scientists conduct their research and reach their conclusions' to proceed to a jury" despite identifying several weaknesses in the experts' opinions. *Id.* at 1139; *see also id.* at 1131 (concerning shortcomings in describing the epidemiological evidence; -id. at 1132 (conducting a Bradford Hill analysis without directly identifying an association in report); id. at 1133 (lacking dose-response data to support conclusions). The Ninth Circuit affirmed the district court's admission of this general causation testimony holding that "the district court's slight 'deference to experts' with 'borderline . . . opinions' was proper under *Daubert*." *Hardeman v. Monsanto Co.*, 997 F.3d 941, 962 (9th Cir. 2021).

Also, "numerous courts have approved opinions . . . despite the absence of conclusive causal evidence" so long as the expert relies on evidence and applies a methodology traditionally used in the field. *McClellan v. I-Flow Corp.*, 710 F. Supp. 1092, 1104 (D. Or. 2010). In *Kennedy*, for example, the Ninth Circuit reversed a district court's exclusion of an expert's opinion on the causation between a collagen product and an autoimmune disorder finding that, "[t]he fact that a cause-effect relationship between Zyderm and lupus in particular has not been conclusively established does not render Dr. Spindler's testimony inadmissible." *Kennedy*, 161 F3d. at 1230. Rather, the expert's reliance on "objective, verifiable evidence and scientific methodology of the kind traditionally used by rheumatologists," satisfied *Daubert. Id.*

In Wendell, the Ninth Circuit again reversed a district court for failing to consider the full picture of an expert's general causation methodology. The Ninth Circuit found that the court had "improperly ignored the experts' experience, reliance on a variety of literature and studies, and review of [plaintiff's] medical records and history, as well as the fundamental importance of

differential diagnosis by experienced doctors treating troubled patients. The district court also overemphasized the facts that (1) the experts did not develop their opinions based on independent research and (2) the experts did not cite epidemiological studies." *Wendell*, 858 F.3d at 1233.

B. <u>JLI's Omnibus Motion to Exclude Certain Opinions on Toxicity and Alleged Health Effects Improperly Requests That the Court Weigh the Evidence on the Relationship Between Juul and Non-Addiction Health Risks</u>

JLI asserts that JUUL is less hazardous than the most dangerous consumer product ever developed: the combustible cigarette. That's not saying much. JLI admits that

Pltf. Ex. 43,

JLI20002862. It admits that "[a]dolescents who tried ENDS reported more respiratory symptoms than those who did not." *Id.* And JLI's quantitative risk assessment, the only piece of science cited by JLI, establishes that JUUL aerosol produced increased respiratory health risks. JLI Ex. 24, Tackett Rpt. at 41-42. In addition to JLI's admissions, epidemiological studies establish a positive association between JUUL aerosol and pulmonary injury, and application of the Bradford Hill factors to the publications and data establishes that the association is causal. Based on the forgoing, Plaintiffs' experts Drs. Pue and Tackett opine that JUUL aerosol can cause or contribute to lung disease.

Despite JLI's admissions and despite solid scientific support for Plaintiffs' experts' causation opinions, JLI seeks exclusion based on the experts' purportedly unreliable methodologies. JLI cites no study, no regulatory authority, and none of its experts. JLI instead relies only on its attorneys' conclusory opinions.

JLI states, "Plaintiffs have no reliable or sufficient epidemiology," without any citation or explanation. (JLI Mot. 3 at 1). To the contrary, Plaintiffs' experts formed their opinions using reliable methodologies and by analyzing hundreds of studies and experiments that establish a positive association between JUUL aerosol and pulmonary injury. In addition to epidemiological studies, they also analyzed human and animal cellular studies, mechanistic data, experimental human studies, animal exposure studies, chemical analyses, dose analyses, and personal observations. The experts also relied on JLI's PTMA. After confirming a positive association

between JUUL and lung injury, they applied the Bradford Hill criteria and concluded that JUUL aerosol can cause or contribute to pulmonary disease and injury. Their opinions are entirely consistent with peer-reviewed systematic reviews of the entire body of evidence that have concluded, "[T]he evidence supports the conclusion of a real relationship between e-cigarettes and respiratory disorders." JLI Ex. 24, Tackett Rpt. at 54.

1. Reliance on Epidemiological Studies and Toxicology by Plaintiffs' Experts is Sound Methodology

JLI states, "Plaintiffs have no reliable or sufficient epidemiology," without any citation or explanation. (JLI Mot. 3 at 1). To the contrary, Plaintiffs' experts formed their opinions using reliable methodologies and by analyzing hundreds of studies and experiments that establish a positive association between JUUL aerosol and pulmonary injury. In addition to epidemiological studies, they also analyzed human and animal cellular studies, mechanistic data, experimental human studies, animal exposure studies, chemical analyses, dose analyses, and personal observations. The experts also relied on JLI's PTMA. After confirming a positive association between JUUL and lung injury, they applied the Bradford Hill criteria and concluded that JUUL aerosol can cause or contribute to pulmonary disease and injury. Their opinions are entirely consistent with peer-reviewed systematic reviews of the entire body of evidence that have concluded, "[T]he evidence supports the conclusion of a real relationship between e-cigarettes and respiratory disorders." JLI Ex. 24, Tackett Rpt. at 54.

Drs. Pue and Tackett relied upon epidemiological studies demonstrating that e-cigarettes cause respiratory disease, which they discuss in their reports and were questioned about in their depositions. *See* JLI Ex. 24, Tackett Rpt. at 50-54; JLI Ex. 21, Pue Rpt. at 21-23; JLI Ex. 50, Pue Dep. at 111:7-112:22, 134:16-135:23, 188:1-206:15; JLI Ex. 53 Tackett Dep. at 75:24-767:20, 22:17-22. For instance, Drs. Pue and Tackett discuss Wills et al., 48 which consisted of a meta-analysis of epidemiological studies, summarization of relevant laboratory studies for interpreting

⁴⁸ Pltf. Ex. 26, Wills et al., *E-cigarette Use and Respiratory Disorders: An Integrative Review of Converging Evidence from Epidemiological and Laboratory Studies*, Eur Respir. J., 57:1901815 (2021).

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the epidemiological findings on respiratory outcomes, and a Bradford Hill analysis, finding "a significant association between e-cigarette use and respiratory disorders in 23 out of 24 studies." JLI Ex. 24, Tackett Rpt. at 50-54; JLI Ex. 21, Pue Rpt. at 21-23. In addition to the Wills metaanalysis, Drs. Tackett and Pue reviewed additional epidemiological studies that were completed before and since Wills. JLI Ex. 24, Tackett Rpt. at 54, JLI Ex. 50, Pue Dep. at 188:1-206:15. Generally, they find positive associations, usually statistically significant, between e-cigarette use and asthma, COPD, and other respiratory diseases. JLI Ex. 24, Tackett Rpt. at 54.

Importantly, as part of their methodology, Plaintiffs' experts also evaluated whether the epidemiological results vary by device type, including honing-in on attributes that JLI claims make JUUL safer than other products. For example, JLI routinely cites to JUUL's controlled heating mechanism as making it safer than other e-cigarettes. Plaintiffs' experts accounted for this and noted that even at low temperatures, toxic chemicals can be formed, which is why the experts examined the presence, absence, and quantification of the toxicants in JUUL's aerosol. JLI Ex. 24, Tackett Rpt. at 12-13, JLI Ex. 21, Pue Rpt. at 4, 10-13. Additionally, they looked at the aerosol particle size to determine where these toxicants would likely deposit in the lung. JLI Ex. 21, Pue Rpt. at 12-13. Dr. Tackett also compared Juul to other e-cigarettes. JLI Ex. 53, Tackett Dep. at 104:17-22. And both experts cited to Chafee et al, 49 which studied use of numerous e-cigarettes, including JUUL, among more than 10,000 adolescents and found that "risk of [] respiratory outcomes is elevated among more frequent e-cigarette users regardless of the device type used." JLI Ex. 24, Tackett Rpt. at 54; JLI Ex. 21, Pue Rpt. at 23.

While Plaintiffs have ample supporting epidemiological studies that validate the experts' opinions on general causation, such studies are not necessary to establish general causation. See

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⁴⁹ Pltf. Ex. 42, Chafee et al., E-cigarette Use and Adverse Respiratory Symptoms Among Adolescents and Young Adults in the United States, J Prevent. Med., 153:106766 (Aug 2021). See also id. at 2 ("Human and animal studies have demonstrated adverse biologic effects of e-cigarette aerosol exposure to respiratory cells and tissues. Case reports have described serious acute respiratory symptoms associated with the use of e-cigarettes. Population-based studies have also described positive associations between e-cigarette use and adverse respiratory health outcomes, including chronic and subclinical conditions.").

Galinis v. Bayer Corp., No. 09-cv-04980, 2019 WL 2716480, at *8 (N.D. Ca. June 28, 2019) (noting "Daubert does not require that a causation opinion be based on an epidemiologic study") (citing Kennedy v. Collagen Corp., 161 F.3d 1226, 1229 (9th Cir. 1998); Wendell, 858 F.3d at 1236). Plaintiff's well-qualified experts have provided detailed and specific reasons for their opinions and have explained how the body of scientific evidence as a whole 50 supports their conclusion.

a. JLI's Arguments Regarding Dose are Unfounded

As a matter of background, JUUL aerosol contains a host of toxicants. Among the most dangerous are carbonyl compounds, generated through the heating of glycerin and propylene glycol, the ingredients that comprise more than 90% of JUUL e-liquids. JLI Ex. 24 Tackett Rpt. at 11. JLI admits, as it must, that carbonyls like formaldehyde, acrolein, acetaldehyde, acetone, and diacetyl are harmful to human health. *See* Pltf. Ex. 44, INREJUUL_00338927.⁵¹ These chemicals all are present in JUUL's aerosol. *See generally*, JLI Ex. 24, Tackett Rpt., JLI Ex. 21, Pue Rpt. at 13. Diacetyl has long been recognized as a lung toxin that causes lung injuries, as have other carbonyls. JLI Ex. 24, Tackett Rpt. at 16-19; JLI Ex. 21, Pue Rpt. at 13; *supra* fn.3. Another carbonyl, methylglyoxal (MGO) is thought to be even more toxic to the lungs than diacetyl. JLI Ex. 24, Tackett Rpt. at 189-20. It too has been detected in JUUL aerosols.

JLI claims that Plaintiffs' experts' opinions on toxicity are unreliable because they fail to account for the relevant threshold dose of JUUL's constituent chemicals and fail to establish that

⁵⁰ See In re Phenylpropanolamine (PPA) Prod. Liab. Litig., 289 F. Supp. 2d 1230, 1242 (W.D. Wash. 2003) at 1242 (rejecting defense Daubert challenges which "isolate these sources [of evidence] rather than considering the whole") In re Zoloft (Sertraline Hydrochloride) Prod. Liab. Litig., 858 F.3d 787, 796–97 (3d Cir. 2017) at 796–797 (citing Milward v. Acuity Specialty Prod. Grp., Inc., 639 F.3d 11, 17 (1st Cir. 2011) at 17 ("[t]he court treated the separate evidentiary components of [the expert's] analysis atomistically, as though his ultimate opinion was independently supported by each."); In re Tylenol (Acetaminophen) Mktg., Sales Pracs., & Prod. Liab. Litig., 198 F. Supp. 3d 446, 458 (E.D. Pa. 2016) at 458; Alexander v. Honeywell Int'l, Inc., No. 1:17 CV 504, 2018 WL 4220628 (N.D. Ohio Sept. 5, 2018); In re Seroquel Prod. Liab. Litig., No. 6:06-MD-1769-ORL-22D, 2009 WL 3806435 (M.D. Fla. June 23, 2009); In re Abilify (Aripiprazole) Prod. Liab. Litig., 299 F. Supp. 3d 1291 (N.D. Fla. 2018).

⁵¹ The FDA HPHC list identifies formaldehyde, acrolein, acetaldehyde and acetone as respiratory toxicants (among other risks), *See* https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/harmful-and-potentially-harmful-constituents-tobacco-products-and-tobacco-smoke-established-list

any individual chemical is present in JUUL aerosol at a toxic level. This argument is flawed in multiple respects.

i) <u>A Dose Threshold for Causation is not a Requirement</u> Under Daubert

JLI asserts that "Plaintiffs' experts must demonstrate that inhalation exposure to a particular chemical at the dose it is present in JUUL aerosol caused the specific harm alleged." (JLI Mot. 3 at 8). This is incorrect—evidence of a toxic dose is not required to satisfy *Daubert*. *See Clausen v. M/V New Carissa*, 339 F.3d 1049, 1059 (9th Cir. 2003). In *Clausen*, which involved claims alleging oil-induced oyster deaths, the court found reliable Plaintiffs' causation expert despite not establishing a "minimum threshold level of oil necessary to cause harm." *Id.* "[W]hile precise information concerning the exposure necessary to cause specific harm to humans and exact details pertaining to the plaintiff's exposure are beneficial, such evidence is not always available, or necessary, to demonstrate that a substance is toxic to humans given substantial exposure and need not invariably provide the basis for an expert's opinion on causation." *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 264 (4th Cir. 1999).

JLI misconstrues Dr. Pue's testimony in claiming that "Pue admits there is no established threshold at which α-dicarbonyls, diacetyl, methylglyoxal, or ENDS exposure cause any of the lung diseases he lists in his report." (JLI Mot. 3 at 9). Dr. Pue testified that there is no dose for these individual chemicals known to be safe versus toxic and that it would be unethical to conduct such a study, but that the data is very strong that e-cigarettes are causally associated with lung disease. JLI Ex. 50, Pue Dep. at 77:2-3, 77:21-78:7, 111:7-22, 164:15-25. A threshold determination is not necessary in cases like this that do not involve common background levels of exposure to a substance, or where there is no identified benign exposure level. *See In re: Zicam Cold Remedy Mktg, Sales Practices, & Prods. Liab. Litig.*, 797 F. Supp. 2d 940, 944-45 (D. Ariz. 2011) (citing *McClellan v. I–Flow Corp.*, 710 F.Supp.2d 1092, 1111 (D. Or. 2010) ("While plaintiffs' experts cannot identify the precise threshold dose of bupivacaine or the length of exposure that triggers irreparable chondrocyte damage, 'Daubert does not require that every aspect of a theory of medical causation be supported by research on the identical point.'" (quoting *Domingo ex rel. Domingo v.*

T.K., 289 F.3d 600, 607 (9th Cir. 2002) at 607)); In re Avandia Mktg, Sales Practices, & Prods. Liab. Litig., 2011 WL 13576 (E.D. Pa. 2011) (denying motion to exclude plaintiffs' general causation experts' opinion about causal connection between Avandia and myocardial infarction without discussion of toxic dose); Bartlett v. Mutual Pharmaceutical Company, Inc., 760 F. Supp. 2d 220 (D.N.H.2011) (denying motion for judgment as a matter of law because plaintiff presented sufficient evidence that drug's risks outweighed its benefits without discussion of toxic dose); In re Fosamax Prods. Liab. Litig., 645 F. Supp. 2d 164 (S.D.N.Y.2009) (denying motion to exclude plaintiffs' general causation experts' opinion that drug can cause osteonecrosis of the jaw without requiring demonstration of toxic dose); In re Neurontin Mktg, Sales Practices, & Prods. Liab. Litig., 612 F. Supp. 2d 116 (D. Mass. 2009) (denying motion to exclude plaintiffs' general causation experts' opinion that Neurontin can increase risk of suicide without determination of dose-response relationship); see also Henricksen v. ConocoPhillips Co., 605 F. Supp. 2d 1142 (E.D. Wash. 2009). Davis v. McKesson Corp., CV-18-1157-PHX-DGC, 2019 WL 3532179, at *10 (D. Ariz. Aug. 2, 2019).

JLI's reliance on *In re Hanford Nuclear Reservation Litig.*, 292 F.3d 1124 (9th Cir. 2002), an environmental exposure case, is misplaced. The *Hanford* plaintiffs alleged injuries from exposure to downwind radiation from the Hanford Nuclear Reservation, and a necessary part of the causation inquiry involved determining the increased relative risk of exposure to radiation beyond that found in the background. Here, there is no background level that needs to be differentiated as the situation is more akin to another product regulated by the FDA: drugs. As explained by one court:

In environmental exposure litigation, plaintiffs may allege injury caused by a substance with which many people interact harmlessly at lesser degrees of exposure. In order to explain how a pervasive substance is harmful, one must show that at a particular level of exposure, the substance becomes toxic. Without requiring this kind of evidence, the door is open to meritless claims based on generally harmless levels of exposure. But that risk is less severe in drug product liability actions. Unlike, for example, the allegation that dust emissions from a factory caused injury, plaintiffs allege anosmia caused by a metered dose of Zicam that they injected directly into their bodies. The level of exposure will be mostly the same for all plaintiffs, and is easily distinguished from the general population's level of zinc gluconate nasal ingestion (i.e., none).

In re: Zicam, 797 F. Supp. 2d at 945–46. Here, JUUL aerosol is inhaled directly into the lungs. The amount of chemicals, relatively speaking, will be mostly the same for all Plaintiffs and will depend on how often and how much they are smoking. See JLI Ex. 24 Tackett Rpt. at 55. That is, while there may be some background level of common exposure to some of the constituent chemicals, there is no background level of exposure to the complex aerosol mixture aerosol produced by the JLI device. As such, Plaintiffs' experts need not establish a threshold dose to establish general causation because the general population is not exposed to background levels of the JUUL aerosol.

ii) Plaintiffs' Experts Took Dose Into Consideration in Opining on the Risks Associated with Diacetyl, Methylglyoxal, and Vanillin

Even if a dose threshold was required under *Daubert*, JLI's criticisms miss the mark because Plaintiffs' experts considered dose in their general causation opinions. JLI's assertions that Dr. Tackett did not "calculate" the dose of diacetyl and vanillin in JUUL are word games. While Dr. Tackett did not "calculate" the dose of diacetyl and vanillin in JUUL, he appropriately relied on the peer-reviewed scientific literature to provide him this information (which demonstrated JUUL vapor exceeded safety thresholds). JLI Ex. 24, Tackett Rpt. at 21, 23-24. Furthermore, Dr. Tackett did an in-depth dose analysis for methylglyoxal because no dose analyses exist in the published literature (and JLI has yet to test quantitatively for methylglyoxal). *See Generally* JLI Ex. 24, Tackett Rpt. at 29. Ultimately, Dr. Tackett applied the same exposure limit recommended for diacetyl—a conservative approach given that methylglyoxal is more toxic than diacetyl and that machine-based studies underestimate the likely amounts of chemicals that users use are ingesting. *Id.* at 31-39. JLI's quibbles with this approach, arguing that the studies Dr. Tackett relies upon are "unreliable and inapplicable." (JLI Mot. 3. at 9). But these sorts of criticisms are appropriate for cross-examination—not for expert exclusion. *See Monroe v. Zimmer U.S. Inc.*, 766 F. Supp. 2d 1012,

⁵² Indeed, JLI criticizes Dr. Tackett's reliance on Hubbs et al., claiming this animal study administered higher levels of diacetyl than found in JUUL. This ignores that JUUL is intended to be inhaled and delivered to the deep lunch 100-200 times each day. Further, JLI fails to mention its own inhalation animal study, which found statistically significant decreased respiratory volumes indicating lung injury. JLI Ex. 24, Tackett Rpt. at. 44-45. Further, in a dissertation study of mice

1030 (E.D. Cal. 2011) (holding shortcomings in study expert relied upon go to weight, not admissibility).⁵³

JLI's argument, which goes only to weight, is that Dr. Tackett's calculation relied on two unreliable and inapplicable studies. First, JLI states that one of the studies Tackett relied on used "potentially" counterfeit pods. Both Dr. Tackett and JLI's toxicology expert compared the methylglyoxal in this study to the two other peer-reviewed studies that tested the presence methylglyoxal in JUUL products, and all three studies were roughly comparable. Ex. 54, Tackett Dep. at 273:3-8, Pltf. Ex. 45, Paustenbach Rpt. at 216. Second, JLI cannot demonstrate that any pods used in this study were counterfeit and being "potentially" counterfeit is not a basis for exclusion under *Daubert*, it is a matter for cross-examination. All of JLI's arguments regarding Azimi et al. go to credibility and weight, not admissibility.

JLI next argues that Dr. Tackett relied on Hubbs et al., which used higher levels of chemicals than those found in JUUL's aerosol. First, JLI misses the point. Hubbs et al. was the first to study the effects of methylglyoxal inhalation on the respiratory system. Pltf Ex. 24, *Flavorings-Related Lung Disease:* A Brief Review and New Mechanistic Data, Toxicologic Pathology 47(8), (2019). The authors found that methylglyoxal is even more toxic than diacetyl, thus Dr. Tackett's use of a diacetyl recommended exposure limit was conservative and appropriate to apply to methylglyoxal. Second, animals are routinely administered higher dosages of chemicals to account for short exposures. JLI Ex. 53, Tackett Dep. at 194:1-4. JLI fails to mention that its own inhalation animal study found statistically significant decreased respiratory volumes, indicating lung injury. Ex. 24, Tackett Rpt. at. 44-45.

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⁵³ JLI ignores that all studies have "flaws" in the sense of limitations that add uncertainty about the

exposed to mango or mint JUUL vapor, mice developed changes in lung physiology indicative of airway resistance and compliance. *Id.* at 43. The author concluded, "Our findings illustrate that a dosage similar to human usage of Juul can negative impact the lung physiology of mice." Olay, J. M., *Effects of Prolonged E-cigarette Exposures on Lung Physiology and Asthmatic Response in a Murine Model.* UC San Diego. ProQuest ID: Olay_ucsd_0033M_19694. Again, this demonstrates that the evidentiary tit-for-tat is best left for cross examination.

proper interpretation of the results. *Reference Manual on Scientific Evidence* at 552. Where an opinion is challenged based on there being "flaws" in a study, the remedy is not preclusion under *Daubert*; rather, the alleged flaws go to the weight of [the expert witness's] opinion, not its admissibility. *See In re Avandia Mktg., Sales Practices & Prod. Liab. Litig.*, No. 2007-MD-1871, 2011 WL 13576, at *9 (E.D. Pa. Jan. 4, 2011).

Dr. Pue reviewed Dr. Tackett's report, discussed the calculations with Dr. Tackett, reviewed the calculations, and had a placeholder to add them to his own report, but he simply overlooked adding them. JLI Ex. 21, Pue Rpt. at 19, JLI Ex. 50, Pue Dep. at 68:1-69:24, 145:7-22, 148:21-151:1. Dr. Tackett is a toxicologist and Dr. Pue is an M.D.; it is not surprising or relevant to a *Daubert* inquiry that Dr. Tackett performed and validated dose calculations upon which Dr. Pue relied.

Dr. Tackett's dose analysis and the published literature have identified three different chemicals individually capable of causing lung injury at the levels users are inhaling. There are over 100 additional chemicals in JUUL's aerosol. JLI Ex. 24, Tackett Rpt. at 41. Dr. Tackett analyzed dose as part of his report, what JUUL is demanding is that Dr. Tackett analyze the dose of every single chemical in JUUL'S aerosol. That is not the *Daubert* standard, nor is it the scientific standard given the plethora of epidemiological studies, laboratory, animal, human, chemical, and dose analyses of individual chemicals demonstrating that JUUl causes lung diseases. JLI takes issue with Plaintiffs' experts not doing the same quantitative risk assessment as JLI. However, the cited "quantitative risk assessment" is flawed and fails to take into account chemicals that JLI chose not to test for like, methylglyoxal, methacrolein, and acetone. JLI Ex. 24, Tackett Rpt. at 41. Even then the quantitative risk assessment establishes that JUUL aerosol produced increased respiratory health risks. *Id.* at 42. Dr. Tackett's methodology and conclusions are sound and consistent with the published literature.

Likewise, JLI's challenges to opinions related to the additive effect of the chemicals in JUUL vapor go to weight and not admissibility. Specifically, Plaintiffs' experts opined that the combination of the chemicals in JUUL aerosol have an additive effect, which increases the risk of harm beyond the risks relating to each chemical individually. This is based upon analysis of the actual chemicals in JUUL aerosol, such as benzoic acid, which enables toxins to reach the deep lung. JLI Ex. 53, Tackett Dep. at 131:18-23. Likewise, methylglyoxal potentiates formaldehyde, a carcinogen. Methylglyoxal inhibits the metabolism of formaldehyde causing formaldehyde to accumulate. *Id.* at 172:18-23. So, the methylglyoxal renders the formaldehyde more hazardous than the formaldehyde would be on its own. JLI does not dispute that Plaintiffs' experts properly

analyzed the available evidence, rather, JLI asserts, *in the abstract*, that is it possible the interaction of chemicals can have an antagonistic rather than additive or synergistic effect. This substantive dispute is yet another topic appropriate for cross-examination and not wholesale exclusion of an expert's opinion. *Planned Parenthood Fed'n of Am., Inc. v. Ctr. for Med. Progress*, 402 F. Supp. 3d 615, 719 (N.D. Cal. 2019) (rejecting exclusion and explaining disputes in data or methodology "are, in the end, the sorts of issues that are appropriately used to discredit or undermine an expert on cross-examination").

b. <u>Plaintiffs' Experts Are Not Required to Perform a PMTA Analysis</u>

JLI claims its PMTA contains the only comprehensive risk assessment in the record and that the opinions of Plaintiffs' experts are unreliable because they did not mirror the PMTA process. First, following the PMTA process is not a requirement under *Daubert*. Second, JLI's risk assessment is not comprehensive because JLI did not include the toxic effects of methylglyoxal, methacrolein, acetone, and a variety of other chemicals in its risk assessment.⁵⁴ JLI Ex. 24, Tackett Rpt. at 41. Finally, as shown above, Plaintiffs' experts applied a reliable methodology to reach their opinions. JLI criticisms that they should have done a different or additional analysis is fodder for cross-examination.

c. <u>JLI's Arguments Regarding Nicotine Toxicity Ignore Long-Established Nicotine Science</u>

JLI claims that "[n]o empirical evidence, whether cited by Plaintiffs' experts or otherwise, demonstrates that nicotine is 'toxic' or causes any chronic health conditions." (JLI Mot. 3 at 12). It is worth noting at the outset that nicotine is an insecticide, secreted by plants in the nightshade family. In addition to effectively killing insects, nicotine is—in sufficiently high doses—lethal to humans. See JLI Ex. 8, Grunberg Rpt. at 16 (citing Bernd Mayer, How Much Nicotine Kills a Human? Tracing back the generally accepted lethal dose to dubious self-experiments in the

⁵⁴ Though JLI's assessment is not comprehensive, nor a requirement under *Daubert*, it is useful insofar as it established that inhaling nicotine-containing JUUL aerosol is likely to have negative consequences for respiratory health and that Juul aerosol produced increased respiratory health risks. JLI Ex. 24, Tackett Rpt. at 41-42.

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nineteenth century, Arch Toxicol (2013)). JLI contends that it is still an open question among researchers whether this poisonous insecticide is "toxic." Nicotine's toxicity has been established for many years and Plaintiffs' experts rely on a vast array of public health research confirming this fact. See, e.g., JLI Ex. 8, Grunberg Rpt. at 11-16; see also JLI Ex. 18, Prochaska Rpt. at 8-12; JLI Ex. 6, Eissenberg Rpt. at 16-18.

Plaintiffs' experts' opinions are consistent with the Surgeon General Reports from 2014 and 2016, which both conclude—on review of relevant studies—that nicotine consumption by adolescents can create lasting damage to brain development and overall health. *See* JLI Ex. 6, Grunberg Rpt. at 15-17. Beyond its acute toxicity in large doses, studies have also confirmed the harms of chronic nicotine exposure to human brains, lungs and reproductive systems. *Id.* at 15-18 (citing multiple sources). Given its status as a reproductive and developmental toxicant, ⁵⁵ it is hardly surprising that Altria warned the users of its own E-Cigarette, the MarkTen that

See JLI Ex. 18, Prochaska Rpt. at

70; JLI Ex. 16, Noar Rpt. at 37 (emphasis added).

Aside from the outdated 1964 Surgeon General's report, JLI cites only two articles—Fagerstrom and Zeller—in support of its argument that nicotine is harmless. Neither article supports its position. The 2013 Fagerstrom paper is entitled "Tobacco Harm Reduction," and discusses nicotine replacement therapy ("NRT") as an alternative *for smokers*. Pltf. Ex. 48, Karl Olov Fagerstrom & Kevin Bridgman, *Tobacco Harm Reduction*, 39 Addictive Behaviors 507. The cherry-picked statement JLI relies on—that nicotine is "itself not very harmful"— is made relative to the harms of smoking cigarettes and cites to a publication addressing nicotine delivery in NRTs, which differ significantly from JUUL in terms of nicotine delivery. Given that "no consumer product kills more people every year than cigarettes," the statement that nicotine is less harmful than cigarettes "is a very low bar, indeed the lowest possible bar." JLI Ex. 18, Proctor Rpt. at 58.

Likewise, the 2017 Zeller paper does not conclude that nicotine is harmless, just that it is *not directly* "responsible for the tobacco caused cancer, lung disease, and heart disease that kill

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⁵⁵ JLI Ex. 8, Grunberg Rpt. at 16.

hundreds of thousands of Americans each year." Pltf. Ex. 49, Mitch Zeller & Scott Gottlieb, *A Nicotine-Focused Framework for Public Health*, 377 New England J. Medicine 1111 (2017). Again, the statement that nicotine is not *as* harmful as cigarettes is not an assertion—let alone a research- backed conclusion—that nicotine is harmless. Indeed, the Zeller article goes on to conclude that the best approach for public health would be to reduce nicotine in all tobacco products. *Id*.

But even if these articles did support JLI's position on nicotine, they would hardly reflect a "scientific consensus," and provide no basis for excluding Plaintiffs' experts' well-supported opinions that nicotine is harmful. (JLI Mot. 3 at 16).

JLI advances two critiques of Plaintiffs' experts' opinions on the danger of nicotine. Neither has merit.

First, JLI argues that Plaintiffs' experts "misattribute" the harms of smoking to the harms of nicotine use. (JLI Mot. 3 at 13). Not so. Plaintiffs' experts rely on research that isolates nicotine use from cigarettes, and often specifically studies the harmful effects of nicotine inhalation devices, like JUUL. See, e.g. JLI Ex. 8, Grunberg Rpt. at 11-15; JLI Ex. 18, Prochaska Rpt. at 8-12; JLI Ex. 6, Eissenberg Rpt. at 16-18. JLI does not dispute the experts' methodology or the studies they cite. Instead, JLI cherry-picks select quotes from the reports of Plaintiffs' experts, Drs. Eissenberg and Casey, which mention the harmfulness of cigarettes, to claim that these experts "misattribute" the harms of cigarettes to nicotine. As discussed above, Plaintiffs' experts describe how nicotine addiction—by itself—harms the brain and the body. That these experts also mention the harms of combustible cigarettes is irrelevant.

Second, JLI asserts that Plaintiffs' experts' present unreliable opinions about "speculative harms" associated with nicotine. Specifically, JLI contends that the opinions (rendered by Drs. Halpern-Felsher and Casey) that nicotine can cause "mood changes, irritability, depression, restlessness, anxiety, problems socializing, stomach pain, dizziness, headaches, and difficulty concentrating" are unreliable because these opinions are not supported by any citation. However, the public health community widely recognizes that nicotine withdrawal and dependence can produce the effects Drs. Halpern-Felsher and Casey detail (*see*, *e.g.*, Surgeon General Report,

Health Effects of E-Cigarette Use Among U.S. Youth and Young Adults, 2016 at 102)⁵⁶ and Dr. Halpern-Felsher string-cites numerous peer-reviewed authorities in support of this opinion. JLI Ex. 10, Halpern-Felsher Rpt. at n.32.

Finally, JLI contends that these specific harms are "speculative" because Plaintiffs' experts have not conducted a Bradford Hill analysis and have founded their opinions solely upon animal studies, gene research, cellular research, or other experimental research. (JLI Mot. 3 at 14). JLI's criticism is inaccurate. As discussed, the opinions as to the harms of nicotine are based on peerreviewed studies that show the effects of nicotine in humans. See e.g., JLI Ex. 8, Grunberg Rpt. at 16-17 (citing studies of nicotine in isolation and discussing how nicotine causes and worsens mood disorders, attention disorders, impulse control, and memory problems); id. (citing studies of nicotine's contributions to developmental abnormalities, neonatal development problems, impairment of endothelial cell function); id. (citing studies finding that nicotine alone damages lung epithelial cells, and prolonged exposure—both in dosage and over time—can result in lung disease and infection). Plaintiffs' experts' opinions are founded on the totality of the studies that have been conducted, which taken together provide reliable support. Reliability is not a matter of checking the basis of expert testimony against a short list of acceptable methodologies; the key determination is "whether the analysis undergirding the experts' testimony falls within the range of accepted standards governing how scientists conduct their research and reach their conclusions." Daubert, 43 F.3d at 1317. When viewed as a whole, the opinions proffered on the toxicity of nicotine are well within the range of accepted and rigorous scientific standards.

d. <u>Plaintiffs' Experts Were Not Required to Determine the Impact of the JUUL Product on Baseline Consumer Risk: Smokers, Former Smokers, and Nicotine Naïve Users</u>

JLI argues that Plaintiffs' experts were required to compare the harms presented by the nicotine in JUUL to the "baseline consumer risk" presented to "smokers, former smokers, and nicotine naïve users." (JLI Mot. 3 at 17). In support, JLI cites to a number of FDA regulations in a thinly veiled attempt to seek reconsideration of this Court's preemption ruling. (JLI Mot. 3 at 17).

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⁵⁶ The DSM-V, a diagnostic tool used by clinicians, use these exact symptoms to diagnose tobacco withdrawal. JLI Ex. 18, Prochaska Rpt. at 21 (explaining DSV-V criteria).

But "[c]hallenges that go to the weight of the evidence are within the province of a fact finder, not a trial court judge. A district court should not make credibility determinations that are reserved for the jury." *City of Pomona v. SQM N. Am. Corp.*, 750 F.3d 1036, 1044 (9th Cir. 2014). While the jury is entitled to determine the evidentiary weight of a comparison (or lack thereof) of the harm of the JUUL product when applied to particular populations, JLI has not and indeed cannot point to any basis in law to require that such comparisons be made to admit expert testimony.

2. <u>Plaintiffs' Experts Presented Reliable Scientific Evidence Establishing</u> General Causation For Various Non-Addiction Diseases

a. <u>Seizures and EVALI</u>

The Parties agree that any issue with expert testimony regarding JUUL's generally causes seizures or EVALI should be deferred until a bellwether plaintiff intends to offer such evidence at trial. As neither seizures nor EVALI are at issue in the upcoming trials, the Court need not address these issue at this time.

b. Asthma

JLI asserts—without citation—that there is no reliable epidemiological evidence linking JUUL use to asthma or asthma exacerbation. (JLI Mot. 3 at 19). JLI's pronouncement runs contrary to the testimony of Drs. Tackett and Pue, and the array of epidemiological and experimental evidence cited by Plaintiffs' experts.

For example, Drs. Pue and Tackett cite a published meta-analysis of recent epidemiological studies that provides "a comprehensive review [of] the association of e-cigarette use with asthma and COPD in human populations." JLI Ex. 24, Tackett Rpt. at 50-54, JLI Ex. 21, Pue Rpt. at 21. The authors of the meta-analysis found that adult and adolescent ENDS users had a statistically significant higher chance of developing asthma. JLI Ex. 24, Tackett Rpt. at 51. Among adolescents, the meta-analysis cites two epidemiological studies that found using ENDS more than doubled the risk of asthma development. *Id.* Among other materials, that article examined "thirty-nine observational studies including 2,111,023 participants and six case studies" investigating the effects of ENDS use in asthmatics. *Id.* Forty-one of those examined studies found that ENDS use was positively associated with asthma exacerbation. *Id.* Plaintiffs' experts' opinions are in line with the

published literature, and JLI cites nothing to contradict these opinions, let alone warrant their exclusion.

c. Other Respiratory Conditions

Plaintiffs' experts opined that JUUL use is linked to "other respiratory conditions"— such as bronchitis, emphysema, and COPD. *See e.g.* JLI Ex. 50, Pue Dep. at 40:23-44:25. These opinions were based on their review of studies, relevant health literature, and their understanding of inhalation of aerosols and pulmonary health. JLI contends that exclusion of these opinions is warranted because none of the studies in and of themselves—conclusively determine that JUUL use *causes* these conditions. (JLI Mot. 3 at 20) (arguing that the studies that find the association of JUUL use with respiratory conditions recognize "their own other limitations on potential causal connections"). JLI's argument misses the mark. JLI does not dispute that Plaintiffs' experts—such as Drs. Pue and Tackett—are qualified to opine of whether JUUL use is injurious to the respiratory system and JLI cites nothing requiring these experts to point to a single population wide study that is, by its own terms, conclusive of the issue. Rather, Plaintiffs' experts are permitted to render an opinion based on their review of a mosaic of a reliable sources, applying their own expertise. That is precisely what Plaintiffs' experts did.

Notably, JLI itself agrees that

Pltf Ex. 43, JLI20002862. Whether, in any given

instance, an individual plaintiff's specific respiratory condition resulted from or was exacerbated by JUUL use will be the subject of a case specific report. It is unclear what purpose JLI's generalized challenge serves, but it does not create any basis for excluding the fundamentally uncontroversial opinions offered by Plaintiffs' experts.

d. <u>Exacerbation of GERD</u>

JLI challenges the basis for Dr. Winickoff's opinion that using JUUL may exacerbate Gastroesophageal Reflux Disease ("GERD"). Specifically, JLI contends that Dr. Winickoff relied solely upon an inapposite study of anesthetized opossums to inform his opinion that nicotine can relax "the lower esophageal sphincter [in humans], causing acid to flow up the esophagus." JLI is

mistaken. Nicotine's relaxing effect on smooth muscles (such as the lower esophageal sphincter) is an established medical fact. This fact is well within Dr. Winickoff's expert knowledge. Dr. Winickoff cited the 1975 study of opossums for the proposition that this effect of nicotine "has been known *for a long time*," not for conclusive evidence of a well understood phenomena. JLI Ex. 25, Winickoff Rpt. at 40. In all events, JLI does not contend that Dr. Winickoff is unqualified to offer opinions on the effect of nicotine on the human body. JLI's side-ways challenge to a citation—for a different proposition—does not provide a basis for exclusion.⁵⁷

3. Plaintiffs' Experts Have Presented Reliable Scientific Evidence Regarding the Impact of Addiction on the Developing Brain

JLI argues that Drs. Winickoff and Levy's opinions that nicotine exposure/addiction impairs the development of the adolescent brain are unreliable because both experts cite studies JLI characterizes as "flawed." (JLI Mot. 3 at 21). As an initial matter, Drs. Winickoff and Levy cite a myriad of authority to support their opinion, and JLI's critique of two studies—even if well-founded—would not support exclusion. Nevertheless, JLI's critique is not well-founded.

JLI claims that Dr. Winickoff's reliance on the 2016 Surgeon General's report discredits his opinions. According to JLI, the 2016 Surgeon General's conclusion that nicotine harms adolescent brain development is defective because it relies on animal research inapplicable to human use of JUUL. (JLI Mot. 3 at 21). This argument ignores the four-page discussion within the 2016 Surgeon General's report supporting its conclusion with a review of numerous studies involving both humans and animals. Pltf. Ex. 39, U.S. Dept. of Health and Human Services, *E-Cigarette Use Among Youth and Young Adults: A Report of the Surgeon General*, Ch. 2 (2016), at 104-07. While the Surgeon General's report states that "any causal argument when examining animal models requires careful consideration" it nevertheless concludes that "in combination with epidemiologic data—such as prevalence, incidence, and strength of association between exposure and outcome—a causal argument can be constructed with literature from animal models representing biologic plausibility." *Id.* at 104-07. This reasoning is aligned with other court's

⁵⁷ As discussed further below, JLI's argument that any opinions related to animal research must be excluded is meritless.

treatment of animal studies under the Daubert standard. See In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 780–81 (3d Cir. 1994) ("While other cases have held that animal studies are inadmissible, these cases are for the most part distinguishable because most involved the exclusion of animal studies in the face of extensive epidemiological data that *failed* to support causation . . . ")(emphasis added).58

As to Dr. Levy's opinion, JLI contends—in conclusory fashion—that the "the studies Levy cites are similarly flawed." (JLI Mot. 3 at 21). JLI does not elaborate on what studies are flawed or how their citation render's Dr. Levy's expert opinion on adolescent brain development unreliable. Nor does JLI address the other, myriad authority Drs. Winickoff and Levy cite. This "fill-in the blanks" argument cannot support exclusion.

Plaintiffs Present Reliable Scientific Evidence Regarding the 4. **Psychological Impact of Addiction**

JLI contends that the expert opinions of Drs. Prochaska, Levy, Grunberg, and Winickoff regarding the psychological impact of nicotine addiction should be excluded wholesale. JLI argues these opinions should be excluded because they fail to employ any "methodology to disentangle the psychological and behavioral disorders that increase the risk that an adolescent uses nicotine, from their opinions that nicotine addiction causes these disorders." (JLI Mot. 3 at 22). In other word, JLI suspects that "the mental health conditions Plaintiffs' experts discuss [could] be a cause of [adolescent] JUUL usage, rather than an effect." *Id.* According to JLI, Plaintiffs' experts' failure to disprove its (unsupported) suspicion warrants exclusion. This argument lacks merit. Plaintiffs' experts do not—as JLI suggests—simply observe that adolescent nicotine users exhibit mood and behavior disorders and conclude that nicotine is to blame. Rather, these experts rely on and engage

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⁵⁸ It is unsurprising that JLI seeks to discredit the applicability of any animal studies. As the Surgeon General's report notes, animal models are particularly useful "when experimentation with humans is not possible (or ethical)." Ptlf. Ex. 39, Report of the Surgeon General, E-Cigarette Use Among Youth and Young Adults, at 107. If JLI had its way, only studies that experimented on kids with JUUL would satisfy Daubert. No such controlled study does, or should, exist. Moreover, the absence of such a study did not prevent the Surgeon General from reliably concluding that "given the existing evidence from human and animal studies of the detrimental impact of nicotine exposure on adolescent brain development, the use of e-cigarettes by youth should be avoided and actively discouraged." *Id.* at 107.

in a sophisticated analysis of the impact chronic nicotine exposure has on adolescent dopaminergic pathways and limbic systems, and the "gross [neuronal] structural changes" that result. Ex. 8, Grunberg Rept. at 18; *see also id.* at 11-14; Ex. 18, Prochaska Rpt. at 39; Ex 13, Levy Rpt. at 23-26, Ex. 32, Shihadeh Rpt. at 5-12. The causal relationship between nicotine and psychological harm, long established through observational study is also confirmed by core neuroscientific understandings. JLI's concern that these experts are simply conflating correlation with causation is unfounded.

Moreover, JLI's argument ignores the evidence that nicotine addiction *worsens* the risk of various psychological disorders, including depression, substance abuse, emotional maladaptation, and attention lapses. (*See, e.g.*, Ex. 8, Grunberg Rpt. at 17-18, Ex. 28, Prochaska Rpt. at 9-10, 15.) Thus, even if certain adolescents *were* predisposed to certain psychological disorders *before* they used JUUL, the psychological harms flowing from their addiction would still be attributable to JLI. It is the classic egg-shell plaintiff situation. *See generally* Restatement (Third) of Torts: Phys. & Emot. Harm § 31, cmt. a (2010) (a "defendant takes the victim as found").

C. <u>Plaintiffs' Experts' Opinions Regarding B.B. Should Not Be Excluded</u>

JLI seeks to exclude Plaintiff's expert's opinions that use of JUUL was a substantial factor in causing B.B.'s alleged injuries by imposing heightened legal and scientific standards and by misstating the record. At best, JLI is wrong on the law and careless with the presentation of facts. Plaintiffs turn first to the law:

1. <u>Legal Standard for Admissibility of Expert Specific Causation</u> Opinions

The inquiry into the admissibility of specific causation testimony is similarly "flexible" Wendell, 858 F.3d at 1232, and "should be applied with a 'liberal thrust' favoring admission." Messick v. Novartis Pharm. Corp., 747 F.3d 1193, 1196 (9th Cir. 2014). The Ninth Circuit recognizes that "[m]edicine partakes of art as well as science," id. at 1198, and "district courts should typically admit specific causation opinions that lean strongly toward the 'art' side of the spectrum." In re Roundup Prod. Liab. Litig., 358 F. Supp. 3d 956, 959 (N.D. Cal. 2019). In other

words, "[u]nder Ninth Circuit caselaw, doctors enjoy wide latitude in how they practice their art when offering causation opinions." *Id.* at 960.

In *In re Roundup Prod. Liab. Litig.*, the court admitted a specific causation opinion based upon the expert's "reliance on his clinical experience, review of a plaintiffs' medical records, and evaluation of the general causation evidence." *Id.* at 960. The Ninth Circuit upheld the admission stating that experts can "rely on clinical experience while conducting differential diagnosis" and that the "district court's suggestion that courts in this circuit can admit opinions 'that lean strongly toward the art side of the spectrum" was an appropriate reiteration of *Daubert* precedent. *Hardeman*, 997 F.3d at 962-63.

Similarly, in *Clausen v. M/V New Carissa*, the Ninth Circuit upheld a district court's admission of expert causation testimony despite the fact that "neither of *Daubert II's* primary criteria for establishing the reliability of expert testimony" was met. 339 F.3d 1049, 1056 (9th Cir. 2003). The research "was not conducted independent of the litigation," nor was the "research 'subjected to normal scientific scrutiny through peer review and publication." *Id.* (citations omitted). However, the Ninth Circuit found that the testimony "was not unsupported by 'scientific knowledge," and that the trial court did not abuse its discretion in concluding that the testimony was reliable under *Daubert. Id.* at 1059, 1061 (citations omitted).

The Ninth Circuit in *Messick* acknowledged the "inherent uncertainty" in determining causation when it held that "we do not require that an expert be able to identify the sole cause of a medical condition in order for his or her testimony to be reliable. It is enough that a medical condition be a substantial factor." *Messick*, 747 F.3d at 1199. The Ninth Circuit held that a "district court abused its discretion in excluding . . . causation testimony when it found that testimony to be unreliable largely because [the expert] could not 'determine in a patient who has multiple risk factors at one time which of those particular risk factors is causing [the ONJ]." *Id.* (holding that "[a] doctor using a differential diagnosis grounded in significant clinical experience and examination of medical records and literature can certainly aid the trier of fact and cannot be considered to be offering 'junk science."").

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The "Ninth Circuit has emphasized that the [Daubert] gatekeeping function is meant to 'screen the jury from unreliable nonsense opinions, but not to exclude opinions merely because they are impeachable." In re Roundup Prod. Liab. Litig., 390 F. Supp. 3d at 1113 (citing Alaska Rent-A-Car, Inc. v. Avis Budget Group, Inc., 738 F.3d 960, 969 (9th Cir. 2013)). Rather, "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." In re Roundup Prod. Liab. Litig., 390 F. Supp. 3d at 1113 (citing Daubert I, 509 U.S. at 596). Accordingly, "causation need not be established to a high degree of certainty for expert testimony to be admissible under Rule 702." Kennedy, 161 F.3d at 1230.

2. The Experts' Specific Causation Opinions are Reliable

Plaintiff's experts' specific causation of Plaintiff B.B.'s injuries are reliable, supported by scientific literature, and grounded in the application of reliable methodology. Plaintiff's highly qualified case-specific experts undertook a comprehensive review of B.B.'s medical records, carefully reviewed all relevant deposition testimony, and most personally interviewed and examined B.B. and her mother. In doing so, Plaintiff's experts considered other factors that could have caused or contributed to B.B.'s conditions and determined that JUUL was a substantial contributing factor in causing B.B.'s injuries. Plaintiff's experts employed standard methodology in examining and diagnosing B.B. as they would in their normal practice. *See e.g.*, JLI Ex. 14, Levy B.B. Dep. 13:1-6; JLI Ex. 55, Winickoff B.B. Dep. 22:20-23:5). In sum, Plaintiff's experts evaluated B.B. using standard methods and reasonably relied on scientific studies to support their opinions on B.B.'s addiction and related conditions.

B.B. alleges two categories of injuries related to JUUL usage: (1) nicotine addiction and associated symptoms and conditions such as anxiety, depression, lack of concentration, mood swings, and decline in academic performance; and (2) other physical injuries, including asthma exacerbation and respiratory issues of difficulty breathing and shortness of breath, GERD exacerbation, and headaches. B.B.'s categories of injuries and the experts that establish specific causation for each injury are addressed in turn, below.

JLI does not dispute B.B.'s diagnosis of nicotine addiction and offers no experts to refute Plaintiff's experts' opinions regarding the severity of her nicotine addiction. (JLI Mot. 3 at 23). Instead, JLI attempts to parse-out for exclusion certain symptoms and conditions associated with nicotine addiction – specifically, depression, anxiety, mood swings, inability to concentrate, and social/academic decline – symptoms and conditions that are common in individuals with severe nicotine addiction, like B.B.

a. The Experts' Case-Specific Causation Opinions About Nicotine Addiction And Associated Symptoms And Conditions are Reliable

Plaintiff's experts, relying on established nicotine addiction science, explain that nicotine addiction is not an isolated condition as JLI suggests; rather, it is a condition that is associated with and leads to disturbances in physical, mental, and emotional health. For example, Dr. Winickoff explains "[n]icotine withdrawal can cause headaches, insomnia, irritability, anxiety, and depression, and these withdrawal symptoms are one of the primary reasons a nicotine addiction is very patient for my patients to overcome." JLI Ex. 24, Winickoff Rpt. at 14. Dr. Prochaska similarly states that "nicotine dependence is characterized by mood disturbance (anxiety, depression), sleep disturbance, poor concentration, agitation, frustration, anger, irritability, and weight gain." JLI Ex. 18, Prochaska Rpt. at 18. Dr. Prochaska further explains that stopping nicotine usage "is associated with deficient neuro-transmitter release and withdrawal symptoms of irritability, anxiety, agitation, depressed mood, difficulty concentrating, insomnia, hunger, and weight gain as well as headache and constipation." *Id.* at 10. Dr. Levy explains that, "high concentrations [of nicotine] can result in symptoms of agitation and anxiety" JLI Ex. 13, Levy Rpt. at 14. and that "nicotine users experience well-known withdrawal symptoms, which can include irritability, appetite stimulation, cravings, headaches, trouble sleeping and anxiety. *Id.* at 16.

At best, telegraphing a point for cross-examination, JLI incorrectly assumes that a clinical diagnosis of a condition is necessary for someone to have suffered from that condition, going as far as claiming B.B. does not even suffer from depression, anxiety, mood swings, or difficulty concentrating because B.B. does not have a clinical diagnosis. However, experts evaluating patients

"may reasonably rely on a patient's self-report of an injury..." *Guthrie v. Ball*, No. 1:11-CV-333-SKL, 2014 WL 11581410, at *18 (E.D. Tenn. Oct. 10, 2014) (citing Fed. R. Evid. 703). In fact, "treating physicians always form their opinions based in part on their patients' self-reported symptoms and background information." *Scherr v. Fleetboston Fin. Corp. Grp. Long Term Disability Plan*, No. CV 06-4050 ABC (CWX), 2008 WL 11438215, at *28 (C.D. Cal. Feb. 8, 2008) (9th Cir. 2009). Experts "are entitled to rely upon statements of the patient in forming opinions regarding the patient's mental state." *Martinez v. Campbell*, No. CV 04-9580-GW CW, 2011 WL 6370111, at *16 (C.D. Cal. Aug. 15, 2011), *report and recommendation adopted*, No. CV 04-9580-GW CW, 2011 WL 6370387 (C.D. Cal. Dec. 20, 2011) (internal citation omitted).

Here, B.B. specifically testified in her deposition that she has suffered from depression and anxiety that she had not suffered before JUUL and that she gets anxious when she is unable to get nicotine. JLI Ex. 57, B.B. Dep. at 126:8-22; 199:16-18. B.B. also stated in her deposition that she suffers from mood swings at she associates with her JUUL usage and that she gets more irritable when she does not have access to nicotine. *Id.* at 124:16-18; 199:11-14. As to lack of concentration, B.B. explained that when she cannot get nicotine, she finds it hard to concentrate and gets distracted more easily, and instead of concentrating on what she was supposed to, she would "be thinking about using JUUL and about how I could use it. I couldn't concentrate because I would always think about it." Id. at 141:15-142:11; 199:7-10. B.B.'s mother specifically explained that when during B.B.'s JUUL usage, she started noticing signs of irritability and withdrawal in B.B. Pltf. Ex. 46, R. Bain. Dep. 155:24-156:3. Further, B.B. directly discussed the symptoms/injuries associated with her nicotine addiction with each Plaintiff expert who evaluated her (Drs. Levy, Prochaska, and Winickoff) as detailed in each expert's report. Accordingly, JLI's assertion that B.B. did not suffer from depression, anxiety, mood swings, or difficulty concentrating due to lack of a clinical diagnosis is off-base. Plaintiff's experts have properly considered B.B.'s self-reported injuries/symptoms in formulating their opinions, as any medical practitioner would.

Depression: JLI inaccurately argues that B.B.'s medical history only shows one episode of depression and that subsequent screenings lacked findings of depression. (Mot. 3 at 26-27). First, JLI mischaracterize B.B.'s depression assessment in December 2018 because the physician during

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visit did not attribute B.B.'s depressed mood to JUUL. But, the physician was not aware that B.B. used JUUL, nor did she ever ask. *See* Pltf. Ex. 46, R. Bain Dep. 156:12-20; JLI Ex. 54, Winickoff Dep. 98:2-8. Second, B.B. scored a 3 on a depression screening on June 21, 2018, during her period of JUUL usage, which Dr. Winickoff opines is a finding of low grade depression. JLI Ex. 54, Winickoff Dep.115:11-23. Thus, B.B. exhibited documented depression symptoms after starting JUUL, in addition to the self-reported depressive symptoms.

Further, Dr. Sharon Levy testified that when B.B. presented for her medical assessment, "her mood was a little bit down . . . and also that her mother's observations included some symptoms that would be characteristic of depression." JLI Ex. 43, Levy B.B. Dep. at 85:7-20. Dr. Levy later stated that "depression is a condition that comes and goes, so it's not unusual for people to have periods where they're expressing symptoms of depression and other periods where they're doing a little bit better." JLI Ex. 43, Levy B.B Dep. 89:10-17. As Dr. Winickoff testified, "the symptoms of depression are different from the diagnosis of depression." JLI Ex. 55, Winickoff B.B. Dep. 119:19-25.

Dr. Winickoff notes in his report many symptoms that are often commonly associated with depression – decreased motivation for activities once enjoyed, less energy, and "guilt and stress around being addicted to a product that she knows she shouldn't be using." JLI Ex. 28, Winickoff B.B. Rpt. at 5. Dr. Winickoff performed testing that revealed that B.B. had moderate depression, reporting "decreased attention, low energy, increased distraction, irritability, and mood-related symptoms for a few years now." *Id.* at 19. Both Winickoff and Levy considered other stressors in B.B.'s life but determined that B.B.'s nicotine addiction contributed to her depression. JLI Ex. 28, Winickoff B.B. Rpt. at 19; JLI Ex. 14, Levy B.B. Rpt. 10-11.

Anxiety: Plaintiffs' experts have a reliable basis to opine that B.B. experienced symptoms of anxiety-related to her severe nicotine addiction. JLI argues that because B.B. has no documented history of clinical anxiety disorders, there is no reliable basis to find that she has suffered anxiety because of her JUUL usage. (Mot. 3 at 27). However, a lack of a clinical diagnosis does not preclude the existence of anxiety as a symptom frequently experienced. In fact, it is well studied

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that anxiety is a common side effect of nicotine withdrawal JLI Ex. 25, Winickoff Generic Rpt. at 23-24; 31.

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Depression: JLI inaccurately argues that B.B.'s medical history only shows one episode of depression and that subsequent screenings lacked findings of depression. (JLI Mot. 3 at 26-27). First, JLI mischaracterize B.B.'s depression assessment in December 2018 because during visit the physician did not attribute B.B.'s depressed mood to JUUL. But, the physician was not aware that B.B. used JUUL, nor did she ever ask. See Pltf. Ex. 46, R. Bain Dep. 156:12-20; JLI Ex. 55, Winickoff Dep. 98:2-8. Second, B.B. scored a three on a depression screening on June 21, 2018, during her period of JUUL usage, which Dr. Winickoff opines is a finding of low-grade depression. JLI Ex. 55, Winickoff Dep.115:11-23. Thus, B.B. exhibited documented depression symptoms after starting JUUL, in addition to the self-reported depressive symptoms.

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B.B. self-reported symptoms of anxiety due to nicotine withdrawals (JLI Ex. 57, B.B. Dep. 199:16-18), and Dr. Prochaska found that that along with anxiety, B.B. experienced symptoms of restlessness, irritability, and difficulty sleeping without nicotine, (JLI Ex. 19, Prochaska Rpt. (B.B.) at 10), symptoms that often accompany feelings of anxiety (JLI Ex. 18, Prochaska Generic Rpt. at 18). In her generic report, Dr. Prochaska outlines the science behind this: "Nicotine use results in

rewarding effects on mood, cognition, stress, and anxiety, facilitated by release of various neurotransmitters (i.e. dopamine, norepinephrine, acetylcholine, glutamate, serotonin, GABA, endorphins." (JLI Ex. 18, Prochaska Rpt. at 39).

Dr. Winickoff performed the GAD-7 on B.B., which rated B.B. as having moderate anxiety. JLI Ex. 28, Winickoff Rpt. (B.B.) at 16. He also notes that "the finding of mental health issues, anxiety, depression, and irritability, in response to using nicotine-containing tobacco products is supported by the medical literature." JLI Ex. 28, Winickoff Rpt. (B.B.) at 20.

Mood Swings: Plaintiff's experts provide a reliable basis to opine that B.B. has suffered mood swings as a result of her JUUL use. Not only because B.B. reports mood swings. JLI Ex. 57, B.B. Dep. 124:16-19, but also because mood swings are a common symptom of nicotine withdrawal, as seen in B.B. specifically. JLI Ex. 25, Winickoff Rpt. at 31 ("Recent work has demonstrated that mood and anxiety disorders, suicidal ideation, and depressive symptoms are all associated with e-cigarette use.); JLI Ex. 18, Prochaska Rpt. at 15 ("Youth and young adults are uniquely at risk for long-term, long-lasting effects of exposing their developing brains to nicotine, including nicotine addiction, mood disorders, and permanent lowering of impulse control.").

JLI argues again that because B.B. has never been diagnosed with mood swings, there is no reliable basis to find that she has suffered mood swings because of her JUUL usage. (JLI Mot. 3 at 27). However, Dr. Levy testified on this issue and stated: "[A]dolescents don't always necessarily come out and say, oh, I'm having a, you know, a certain mental health disorder, like a mood swing. There was a period where [B.B.] was clearly very moody and ended up seeing a healthcare professional for it." JLI Ex. 43, Levy Dep. 84:2-15. Dr. Prochaska also opined that "Nicotine withdrawal is characterized by mood disturbance (anxiety, depression), sleep disturbance, poor concentration, agitation, frustration/anger/irritability, and weight gain." JLI Ex. 18, Prochaska Rpt. at 18.

JLI also mischaracterizes Dr. Winickoff's testimony regarding mood swings. Dr. Winickoff does not in any way indicate that B.B. did not experience mood swings. JLI Ex. 28, Winickoff Dep. at 88:7–89:18. In fact, he recalled that B.B. reported experiencing symptoms related to mood swings. JLI Ex. 55, Winickoff Dep. at 89:19-90:6; JLI Ex. 28, Winickoff Rpt. (B.B.) at 5. Further,

Dr. Winickoff noted in his generic expert report that the Surgeon General Report from 1988 listed 3 primary criteria for nicotine dependence, which includes "psychoactive (mood-altering) effects." JLI Ex. 25, Winickoff Rpt. at 24.

JLI similarly mischaracterizes Dr. Prochaska's testimony regarding mood swings. In deposition, JLI counsel asked Dr. Prochaska about mood swings being an "emotional lability." JLI Ex. 48, Prochaska Dep. at 143:23–144:7. While Dr. Prochaska admits she had not seen a diagnosis for this specifically, she did point out, that "when [B.B.] stops her nicotine use, she has mood lability and then she has quickly returned to her nicotine use." *Id.* Dr. Prochaska continues to state that she would treat B.B. mood lability with cessation medication since mood lability, i.e. mood swings, is a common symptom of nicotine addiction. *Id.*

Concentration/Cognitive Issues: JLI again argues that without a clinical diagnosis of an inability to concentrate or cognitive impairment, there is no reliable basis for Plaintiff's experts' opinion. However, this is also a symptom that is well-documented to be common to nicotine withdrawal. Dr. Levy notes that "nicotine exposure is associated with cognitive decline, lower psychomotor speed and decreased cognitive flexibility in adulthood." JLI Ex. 13, Levy Rpt. at 40. Additionally, Dr. Levy opines that "[t]he very high peaks and low troughs in nicotine that can be experienced when people use JUUL result in impaired concentration." Id. at 41. Dr. Winickoff also supports this opinion and stated: "In very recent human epidemiological studies, e-cigarette use in the general population has been associated with cognitive complaints, and e-cigarette use during adolescence has been strongly associated with serious difficulty concentrating, remembering, and making decisions." JLI Ex. 25, Winickoff Rpt. at 3. Dr. Prochaska also highlights that "When nicotine levels decline, brain function is disrupted, withdrawal symptoms develop, reversing nicotine's positive effects." JLI Ex. 18, Prochaska Rpt. at 39.

B.B. self-reports the effects of nicotine on her ability to concentrate in her deposition, "for example, at school, instead of concentrating on what I'm supposed to be doing, I'd be thinking about using JUUL and about how I could use it. I couldn't concentrate because I would always think about it." B.B. also described it as "just getting distracted more easily." JLI Ex. 57, B.B. Dep.

at 142:2-11. B.B. specifically reported to Dr. Winickoff that she experienced lack of concentration, trouble focusing and sitting still. JLI Ex. 55, Winickoff Dep. at 90:15–91:5; 92:13-18.

JLI cherry-picks one statement that Dr. Winickoff made in his deposition that he did not formally test B.B. for ADHD and claim that this establishes that B.B. has no formal diagnosis. However, Dr. Winickoff explained in his deposition that "a clinical problem is different from a formal diagnosis of ADHD... I did not a formal clinical assessment of ADHD. But for me, as a clinician in years of practice, if a child is having trouble focusing trouble sitting still, trouble concentrating and they define that as a problem for them, then I make note of it and we address that." JLI Ex. 55, Winickoff Dep. at 95:13-20. Dr. Winickoff recognized B.B.'s issues with focus and concentration and noted them in his report. Thus, Plaintiff's experts reliably offer the opinion that B.B. suffers from difficulties concentrating and cognitive effects because of JUUL.

Academic and Social Decline: JLI argues that Dr. Levy does not account for other factors for B.B.'s decline in her social and academic environments, stating her only methodology is anecdotal and just "what happens" from addiction. (JLI Mot. 3 at 28-29). JLI further argues that Dr. Levy did not properly evaluate other psychosocial stressors in B.B.'s life. However, in her report, Dr. Levy goes through several psychosocial stressors that have occurred in B.B.'s lifetime. JLI Ex. 14, Levy Rpt. (B.B.) at 7-8. B.B. does not have knowledge of most of these psychosocial stressors, and thus it is hard to say to what degree they affected her if she did not even report these herself and does not seem to recall them. Nonetheless, Dr. Levy incorporates them into her analysis. Dr. Levy also considers several other factors in her expert report that are likely to have affected B.B.'s social and academic course, acknowledging that COVID and virtual learning likely impacted B.B.'s performance in sports and academically. Dr. Levy considers other potential causes, but ultimately finds that "to a reasonable degree of medical certainty that JUUL use and subsequent addiction was a substantial contributing factor in her declining function in both academics and sports." JLI Ex. 14, Levy Rpt. (B.B.) at 11.

Additionally, Dr. Levy reports that when she met with B.B., she recalls B.B. sharing that she has experienced a significant change in friend groups since starting JUUL, and now all of her friends are friends who also vape. JLI Ex. 14, Levy Rpt. (B.B.) at 6-7. Thus, even B.B. can

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acknowledge the social changes her addiction has instigated. Dr. Levy thoroughly and explicitly considered other potential causes of B.B.'s social and academic decline; she did not ignore them as JLI suggests. Dr. Levy's methodology is not anecdotal. Utilizing a thorough review of the B.B.'s academic, medical, and factual record, including extensively interviewing B.B. and her mother regarding B.B.'s academic and athletic decline, reached the conclusion that B.B.'s JUUL use and nicotine addiction was a substantial contributing factor to B.B.'s declining academics and athletics.

b. The Experts' Case-Specific Causation Opinions About BB's Other Physical Injuries are Reliable

Asthma: JLI's oversimplification of the facts mischaracterizes Dr. Levy's opinions that JUUL exacerbated B.B.'s respiratory conditions. Dr. Levy specifically considered and differentiated the frequency and severity of B.B.'s pre-JUUL and post-JUUL asthmatic events, noting increased treatment for breathing issues post-JUUL initiation and new medications required to treat said issues. See JLI Ex. 43, Levy B.B. Dep. at 99-102. Dr. Levy's opinions regarding asthma and respiratory issues are based on a full review of B.B.'s medical records and evaluating and interviewing B.B. and her mother. Dr. Levy testified on the difference in B.B.'s presentation and what is typically seen in adolescents with asthma: "I think that the number of visits that [B.B.] had, you know, for upper respiratory you would expect to be decreasing as kids get a little bit older. And, in fact, in [B.B.], you know, I think that they really start increasing." Id. at 99:19-24. Moreover, Dr. Levy continued that "[I]t's really very common for people to have less problems with asthma overall, with asthma exacerbations overall as they get older." *Id.* at 100:4-10. Dr. Levy makes clear that asthmatic issues would typically decrease as a typical child with asthma grew older. But that did not happen for B.B. In fact, the opposite asthmatic conditions occurred. B.B. experienced higher asthmatic exacerbations which Dr. Levy connected to B.B.'s JUUL usage. Specifically, Dr. Levy noted that:

Review of medical records identifies an increase in the number of urgent care doctor visits for upper respiratory symptoms which began after [B.B.] began vaping. Pharmacy records indicate that [B.B.] was prescribed oral steroids 9 times in the 4.5 years between May 2011 and November 2016 (prior to vaping) and 7 times in the 2.5 years between February 2018 and October 2020 (after starting vaping), and inhaled fluticasone was initially prescribed in 2018.

JLI Ex. 14, Levy Rpt. at 4.

B.B.'s testimony also supports Dr. Levy's conclusion, as B.B. noted that her asthmatic problems experienced as a child essentially went away and returned only after she started JUUL. JLI Ex. 57, B.B. Dep. at 139:13-140:5. In her deposition, B.B. answered "I never had problems with [asthma] until – I mean, I had them when I was younger, but after they went away I never really had problems with it until after I started using JUUL." *Id.* at 139:13-21.

The timeline of B.B.'s JUUL initiation and the uptick in doctor's visits for asthmatic symptoms correlate with B.B.'s JUUL addiction. Dr. Levy's testimony clearly outlines that B.B.'s asthma symptoms worsened after beginning vaping, as noted in the medical records and as reported by B.B. Further, "...to a reasonable degree of medical certainty, [B.B.]'s use of JUUL was a substantial factor in exacerbating [B.B.]'s asthma symptoms and incidences." JLI Ex. 14, Levy B.B. Rpt. at 10.

Plaintiff's expert Dr. Alicia Casey also offers reliable testimony linking B.B.'s JUUL use to asthma exacerbations. The thrust of JLI's argument to exclude Dr. Casey's opinions are that she did not consider B.B's obesity or other environmental factors, which is incorrect. Dr. Casey reviewed all of the available medical records to inform her opinion, which included records providing B.B.'s weight at medical appointments. Dr. Casey establishes that after B.B. started JUUL, B.B. had an increase in pulmonary and medical visits for asthmatic symptoms – shortness of breath, wheezing and chest tightening. JLI Ex. 2, Casey B.B. Rpt. at 3. Additionally, Dr. Casey keys in on the fact that B.B. was never prescribed a steroid inhaler until after she started using JUUL. *Id.* In the context of B.B.'s full medical history (including B.B.'s fluctuating weight), she attributes B.B.'s increased respiratory symptoms and medical attention to B.B.'s extensive JUUL use.

Additionally, Dr. Casey considered and ruled out other environmental factors for B.B.'s increased respiratory symptoms. She considered B.B.'s testimony that seasonal allergies "can affect [B.B's] asthma depending on how bad the pollen is around their area" which "occurs in the spring." JLI Ex. 2, Casey B.B. Rpt. at 4. Dr. Casey ruled this potential cause out and testified that the allergies do not cause shortness of breath, cough, and congestion, which are the symptoms B.B.

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experienced because of JUUL. JLI Ex. 57, B.B. Depo. at 140-141. She not only rules out other potential causes, but she points to direct causes in JUUL. Specifically, she establishes JUUL's own research scientists found that JUUL aerosol contained "formaldehyde and other harmful and potentially harmful chemicals," and that later studies showed these "were even more prevalent than premarket tests suggested." JLI Ex. 2, Casey B.B. Rpt. at 6. Dr. Casey connects the presence of formaldehyde, vaping, and increased asthmatic symptoms in B.B. to these studies. *Id.* Ultimately, Dr. Casey concludes that B.B. experienced asthma exacerbation since starting JUUL and that JUUL was a substantial contributing factor in this condition. . JLI Ex. 57, B.B. Dep. 139:22 – 140:9; Pltf. Ex. 46, R.Bain Dep. at 168:20 – 169:12; JLI Ex. 2, Casey B.B. Rpt. at 8.

Dr. Winickoff likewise offers reliable opinions regarding B.B.'s asthma exacerbation and respiratory symptoms. While he acknowledged that B.B. had "mild asthma" prior to initiating JUUL use, that there was nothing he saw in her medical record prior to JUUL initiation "that indicated like a real shortness of breath or trouble breathing." JLI Ex. 55, Winickoff B.B Dep. 11/12/21, Vol. 2, at 134:12-13, 136:20-137:6. He testified that after initiating JUUL, B.B. experienced "more asthma symptoms, worsening symptoms, and required more medication after she began Juuling." JLI Ex. 55, Winickoff B.B. Dep. 11/12/21, Vol. 2, at 138:14-19. Dr. Winickoff grounded this opinion in scientific research that vaping puts B.B. at higher risk of worsening her existing respiratory conditions due to aerosol exposure. JLI Ex. 25, Winickoff Generic Rpt. at 34. As Dr. Winickoff established in his generic report, which is incorporated in his B.B. report, it is well established that e-cigarettes are particularly harmful for youth with asthma because JUUL usage can increase the frequency of asthma attacks. *Id.* at 34-35.

JLI offers no legal support to exclude Dr. Winickoff's respiratory opinions. Nor could it. Instead, JLI throws one hypothetical after another to try and undermine his methodology and opinions. JLI faults Dr. Winickoff for allegedly not definitively determining whether B.B. actually used medications prescribed by multiple providers for increased asthma and respiratory complications. Dr. Winickoff offers the opinion, based of medical history, personal evaluation, and experience, that B.B. suffered increased respiratory issues because of JUUL. JLI's argument about whether B.B. ingested prescribed medication and inhalers is inapposite.

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GERD. As to exacerbation of GERD, Dr. Winickoff's medical opinion that JUUL caused B.B. to experience an exacerbation of GERD is grounded in both scientific literature and reliable methodology. JLI asserts that Dr. Winickoff's methodology is not based on scientific literature. (Motion 3 at 25). However, Dr. Winickoff establishes that "Worsening GERD in response to tobacco product use is consistent with the medical literature." JLI Ex. 28, Winickoff B.B. Rpt. at 19. In deposition, he points directly to this scientific medical literature when stating, "It's not just a theory, it's actually known since the 1970s that nicotine loosens the lower esophageal sphincter, allowing acid to come up the esophagus[.]" JLI Ex. 55, Winickoff B.B. Dep. at 147:17-20. Dr. Winickoff clearly relies on scientific literature to form his methodology and opinion that JUUL exacerbated B.B.'s GERD.

JLI employs a "see what sticks" approach to further try and debunk Dr. Winickoff's opinion regarding B.B.'s exacerbation of GERD. First, JLI presents the red-herring that B.B. has a family history of GERD and was diagnosed with GERD prior to becoming addicted to JUUL. Plaintiff's position is not that JUUL use initiated GERD in B.B., nor does Dr. Winickoff opine that JUUL usage caused B.B. to initially suffer from GERD. Dr. Winickoff's opinion and Plaintiff's allegations are only that JUUL usage exacerbated B.B.'s GERD. A previous diagnosis and family history are both irrelevant to whether B.B.'s addiction to JUUL exacerbated her GERD.

Second, JLI attempts to discredit Dr. Winickoff for not considering that "B.B. is obese[.]" (Mot. 3 at 26). JLI points the Court to Dr. Winickoff's deposition and states that he testified that he did not consider B.B.'s "obsesity." *See Id.* A closer examination of the testimony shows that, once again, JLI misstates the record.

In the testimony JLI cites to the Court, Dr. Winickoff is answering questions about obesity contributing to *asthma exacerbation*, **not** *exacerbation of GERD*. *See* JLI Ex. 55, Winickoff B.B. Dep. at 134:9-136:6 (Winickoff recognizing that one factor that could lead to asthma exacerbation is obesity). In fact, <u>nowhere</u> in the deposition is Dr. Winickoff asked whether he considered B.B.'s alleged obesity in reaching the medical opinion that JUUL use exacerbated B.B.'s GERD. In his report, though, he considers and rules out other relevant factors before ultimately concluding that JUUL use "increased [B.B.'s] GERD frequency and severity." JLI Ex. 28, Winickoff B.B. Rpt. at

18-19 (ruling out short term NSAIDS usage as the cause of B.B. GERD exacerbation). JLI's contention that Winickoff ignored this "other relevant factor" is entirely unsupported. JLI's arguments regarding Winickoff's opinion that JUUL exacerbated B.B.'s GERD are without merit.

Headaches. JLI next attacks Dr. Winickoff's opinions that B.B. has suffered headaches because of her nicotine addiction caused by JUUL. JLI asserts that Dr. Winickoff does not distinguish the headaches B.B. experienced that pre-dated JUUL from the headaches that B.B. experienced from JUUL. (Motion 3 at 34). This is a blatant misrepresentation as Winickoff's B.B. specific expert report that sets forth his methodology and provides a detailed distinction and diagnoses. JLI Ex. 28, Winickoff B.B. Rpt. at 17-18. Specifically, Winickoff describes the three causes of headaches B.B. experienced to differentiate the types: migraine headaches, headaches due to infections, and nicotine withdrawal headaches. JLI Ex. 55, Winickoff B.B. Dep. at 145:14-146:4. Dr. Winickoff analyzed the pattern of B.B.'s headaches over time, including what precipitates and alleviates her headaches. JLI Ex. 28, Winickoff B.B. Rpt. at 17-18.

Winickoff acknowledged that while B.B. experienced headaches before starting JUUL, those headaches were typically associated with another direct cause. Winickoff also acknowledged that while B.B. has a history of migraine headaches, the headaches she has experienced because of JUUL have not been accompanied by visual symptoms and light sensitivity, which are symptoms common to migraines specifically. *Id.* Since becoming addicted to JUUL, B.B.'s headaches have been often unrelated to any infection, aura, or light sensitivity and appear to subside with over-the-counter medication or nicotine inhalation from an e-cigarette. Additionally, these headaches often present in the morning and are alleviated with nicotine use, which is a sign consistent with nicotine withdrawal symptoms. JLI Ex. 28, Winickoff B.B. Rpt. at 4; JLI Ex. 54, Winickoff Dep. at 143:14-147:4. Further, B.B. has experienced these headaches more frequently since initiating JUUL. *Id.* at 6. Winickoff's testified that this opinion is directly supported in the scientific community, stating that "there's a large literature about tobacco product association with headaches[.]" JLI Ex. 54, Winickoff at 143:22-144:10.

Accordingly, Plaintiff's experts offer reliable opinions on the physical symptoms and injuries JUUL caused B.B. to suffer. As such, the Court should deny JLI's attempt to exclude these opinions.

3. There Is Reliable Support for Medical Monitoring Opinions

JLI essentially contends that because Plaintiff failed to meet her burden to produce evidence sufficient to substantiate certain elements of her independent cause of action for medical monitoring, any related opinions regarding Plaintiff's need for long-term medical testing and treatment are unreliable and, therefore, properly excludable under *Daubert*. "California courts have not set so high a bar for testimony concerning future medical expenses." *Martinez v. United States*, No. 116CV01556LJOSKO, 2019 WL 266213, at *10–11 (E.D. Cal. Jan. 18, 2019).

As a preliminary matter, in her summary judgment responses, Plaintiff abandoned her independent cause of action for medical monitoring. (ECF Nos. 2784, 2791). Yet settled law nonetheless affords Plaintiff the opportunity to obtain damages for future medical expenses at trial irrespective of whether she maintains a claim for medical monitoring. *See* Minor's Damages, Tenn. P. Civ. Jury Instr. 14.26; Medical Expenses—Past and Future (Economic Damage), Cal. P. Civ. Jury Instr. 3903A. "Reliable expert testimony need only be relevant, and need not establish every element that the plaintiff must prove, in order to be admissible." *Primiano v. Cook*, 598 F.3d 558, 565 (9th Cir. 2010). As described in greater detail below, record evidence more than establishes a predicate for the relevance of evidence regarding Plaintiff's ongoing need for cardiovascular, pulmonary, and neurobehavioral evaluation and treatment.

Youth with a history of vaping are more likely to develop chronic respiratory issues when they are vaping or have vaped in the past. JLI Ex. 2, Casey B.B. Rpt. at 6-7. Because of JUUL's ease of use, high nicotine content, and ease of concealment, it is not uncommon to see adolescents with a high frequency of high-quantity JUUL use. JLI Ex. 1, Casey Generic Rpt. at 14. Plaintiff often used large quantities of JUUL, and her pulmonary symptoms have worsened since she started vaping. JLI Ex. 2, Casey B.B. Rpt. at 3. Tobacco use has been shown to remodel the cellular molecules in a fashion regarded as important to the development of chronic lung diseases like bronchiectasis and emphysema, disorders that lead to the development of chronic obstructive

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pulmonary disease ("COPD") and cause significant long-term morbidity and mortality. JLI Ex. 2, Casey Rpt. at 28. Life-threatening asthma exacerbations have also been reported amongst teens with a remote history of asthma, who had well-controlled symptoms for many years, with a history of vaping, just like B.B. *See id.* at 28-29. In one study, adults that were former e-cigarette smokers were more likely to report respiratory disease, even when researchers controlled for a history of combustible cigarette smoking. (*See Id.* at 27). Literature reflects that exposure to JUUL's aerosol has been reported to cause wheezing, pulmonary inflammation, impaired pulmonary gas exchange, as well as chronic lung effects. JLI Ex. 13, Levy Rpt. at 21. Until Plaintiff overcomes her nicotine addiction, she will remain at increased risk of serious viral and bacterial respiratory infections—such as bronchitis, pneumonia, and sinusitis. JLI Ex. 28, Winickoff B.B. Rpt. at 21. The fact that Plaintiff's test results from her pulmonary assessment at the Vanderbilt University Hospital were normal is not dispositive of the concern for chronic pulmonary issues in the future. *See Id.* at 24. Consequently, until Plaintiff is successfully able to overcome her nicotine addiction and stop vaping, she is recommended to receive pulmonary evaluations every three-to-four months for her symptoms, and more frequently in instances of acute increase. JLI Ex. 2, Casey B.B. Rpt. at 8.

Regarding future medical expenses related to cardiovascular care, in 2019, heart disease was the leading cause of death in the United States, and cigarette smoking is a major contributor in the development of heart disease. JLI Ex. 1, Casey Rpt. at 34. "[G]iven the well-known risks of nicotine as a vasoconstrictor causing hypertension among other adverse effects, there is a cardiac risk to users of JUUL." JLI Ex. 13, Levy Rpt. at 21. People who use e-cigarettes are at high risk of progressing to combustible cigarettes. JLI Ex. 28, Winickoff B.B. Rpt. at 22; JLI Ex. 13, Levy Rpt. at 41, 44. If Plaintiff's nicotine addiction remains unabated, and she does progress to combustible cigarette use, she will be at substantially increased risk of heart disease, stroke, lung diseases, diabetes, chronic bronchitis, COPD, and a ten-year reduction in life expectancy. JLI Ex. 28, Winickoff B.B. Rpt. at 22-23. Therefore, it is recommended that Plaintiff be monitored for cardiac risk factors and heart disease. JLI Ex. 14, Levy B.B. Rpt. at 10.

Worsening gastroesophageal reflux disease ("GERD") in response to tobacco use is also consistent with medical literature. JLI Ex. 28, Winickoff B.B. Rpt. at 19. Given her almost-daily

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GERD symptoms, Plaintiff is recommended to use a proton pump inhibitor to block a significant portion of her stomach acid, the use of which requires subsequent evaluation and monitoring by a gastroenterologist, who will also need to evaluate whether Plaintiff has had any precancerous changes to her esophagus from the reflux she has already experienced. (See Id. at 23).

Nicotine exposure has been strongly associated with anxiety, depression, altered behavioral patterns, and other long-term, adverse mental health effects. JLI Ex. 25, Winickoff Rtpt. at 31. Nicotine toxicity leads to significant functional impairment, which can result in missed days of school, interference with activities of daily living, withdrawal from activities. JLI Ex. 1, Casey Rpt. at 14. Plaintiff's psychological outlook has suffered in a myriad of ways because of her JUUL use, including impairments in concentration, recurrent withdrawal symptoms, symptoms of a mood disorder, decline in academic function, loss of interest in hobbies and abnormally decreased engagement with family (beyond what would be expected during adolescence), all of which has substantially altered her life trajectory. JLI Ex. 14, Levy B.B. Rpt. at 10-11. As a result, Plaintiff is a much higher risk of developing a mood disorder, which thus requires more extensive medical evaluation, treatment and follow-up. JLI Ex. 1, Casey Rpt. at 13-14; JLI Ex. 28, Winickoff B.B. Rpt. at 23-24. Plaintiff has more than established the predicate to connect her experts' knowledge of the harms she is likely to face if her nicotine addiction continues unabated to the long-terms risks for which she seeks further evaluation and treatment.

D. Conclusion

For the foregoing reasons, JLI's Motion #3 should be denied.

VIII. JLI MOTION #4: NARRATIONS, INTENT, STATE-OF-MIND, AND LEGALITY

Under the guise of *Daubert*, JLI seeks to preclude traditional expert testimony not on grounds that relate to these qualifications or methodology employed by any one of Plaintiffs' experts but on aversion to the message they convey. Not even the Supreme Court supports this request. "The focus [of the Rule 702 inquiry] must be solely on principles and methodology, not on the conclusions they generate." Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 595 (1993). District courts regularly manage the exclusion of relevant testimony through in limine motions or objections at trial, which is the result this Court should reach. At worst, JLI's motion

inappropriately seeks to exclude relevant evidence that is damaging to its defense, not because it is legally prejudicial, but because it proves JUUL's conduct to be reprehensible. Facts, being stubborn things, are not so easily cast aside. At best, JLI's motion is premature as it presents speculative objections against hypothetical testimony, when the matter is best addressed in the context of trial where actual circumstances can be evaluated to determine if any prejudice outweighs the probity of the testimony offered.

The gist of JLI's motion is that experts cannot provide factual narratives to support their opinions, opine about what JLI and its employees knew or should have known based on their communications, or use words or phrases that relate to any legal determination in this case. JLI's arguments are frivolous. Initially, experts *must* provide the factual support for their opinions. As to the state-of-mind opinions, JLI does not challenge the factual support for these opinions about what its officers knew and should have known—based upon JLI's own internal communications. Furthermore, Federal Rule of Evidence 704(b) only bars experts in *criminal* cases from testifying about a *criminal* defendant's state of mind. The text obviously permits similar testimony in *civil* cases. As to JLI's objection that certain opinions reach ultimate issues in this case, Rule 704(a) expressly rejects that argument and permits experts to opine on ultimate issues. In addition, as explained herein, the caselaw in this Circuit rejects each of JLI's arguments.

Beyond the substantive flaws in JLI's arguments, JLI's "concerns here [are] improper for a *Daubert* motion and best raised as an objection at trial." *In re Glutametza Antitrust Litig.*, No. C 19-05822 WHA, 2021 WL 3773621, at *20 (N.D. Cal. Aug. 25, 2021). Because JLI only "makes generic complaints about the types of opinions and categories of testimony," this Court should deny its motion as undeveloped and premature. *In re Nat'l Prescription Opiate Litig.*, No. 1:17-MD-2804, 2019 WL 4165021, at *3 (N.D. Ohio Sept. 3, 2019). In denying a similar motion, the *Opiate* court explained that "[i]n essence, Defendants are asking the Court to issue an advisory ruling excluding unspecified: (i) narrative testimony; (ii) testimony as to knowledge, intent, and state of mind; and (iii) 'legal opinions' without detailing the specific opinions or testimony." *Id.* As in *Opiate*, this Court should decline to "make non-specific rulings on the record before it." *Id. See also In re DePuy Orthopaedics, Inc. Pinnacle Hip Implant Prod. Liab. Litig.*, 2016 WL 6271474,

at *4 (N.D. Tex. Jan. 5, 2016) (citing *In re Yasmin & YAZ (Drospirenone) Mktg., Sales Pracs. & Prods. Liab. Litig.*, No. 09-02100, 2011 WL 6302287, at *8 (E.D. Ill. Dec. 16, 2011)); *In re Xarelto (Rivaroxaban) Prod. Liab. Litig.*, 2017 WL 1352860, at *2 (E.D. La. Apr. 13, 2017) ("Defendants' [state of mind] arguments go to the witness's conclusions, not her methodology or qualifications, and accordingly may be dealt with by cross-examination at trial."). For these reasons, this Court should deny JLI's motion.

A. <u>Plaintiffs' Experts Properly Discuss the Facts That Support Their Opinions.</u>

JLI challenges "[a]t least nine of Plaintiffs' experts, namely Chandler, Jackler, Proctor, Ribisl, Drumwright, Grunberg, Lindbloom [sic], Levy, and Woolley" for including factual narratives in their reports. (JLI Mot. 4 at 2). To support its sweeping argument that each of Plaintiffs' experts should be totally excluded from offering testimony, JLI employs generalizations concerning whole sections of various experts' reports. JLI follows this with scattershot attacks (often unrelated to JLI's central contention about narrative testimony) on methodology and qualifications, making it difficult to even decipher the exact relief that JLI seeks as to each expert. Regardless, these arguments are as meritless as they are undeveloped.

On the merits, JLI's argument is frivolous because experts *must* provide the factual basis for their opinions. As this Court recently observed, "[i]t is common, indeed required, under Rule 26(a)(2), for an expert to summarize the facts and data considered in their report. [An expert's] testimony at trial must remain tethered to the expert opinion he provides, but he must be allowed to discuss facts apropos to those opinions." *In re Glumetza Antitrust Litig.*, No. C 19-05822 WHA, 2021 WL 3773621, at *20 (N.D. Cal. Aug. 25, 2021) (denying motion to exclude expert testimony "regarding plaintiffs" 'preferred view' of the factual narrative"). An expert "of course, [is] allowed to identify the facts (documents, testimony) that support his otherwise permissible opinions. Defendants are free to challenge [the expert] on the stand regarding his interpretations of those documents and testimony." *United Food & Com. Workers Loc. 1776 & Participating Emps. Health & Welfare Fund v. Teikoku Pharma USA*, 296 F. Supp. 3d 1142, 1194 (N.D. Cal. 2017). *See also In re 3M Combat Arms Earplug Prod. Liab. Litig.*, No. 3:19MD2885, 2021 WL 765019, at *41 (N.D. Fla. Feb. 28, 2021) (finding experts' opinions were "not unhelpful narrative accounts but are

instead commentary on evidence that explains the factual bases of their opinions [...]"); Scentsational Techs., LLC v. Pepsi, Inc., No. 13-CV-8645 (KBF), 2018 WL 1889763, at *4 (S.D.N.Y. Apr. 18, 2018), aff'd 773 F. App'x 607 (Fed. Cir. 2019) ("It is certainly the case that an expert may and often must rely on facts—and that the expert will state them in a report.").

Moreover, factual narrations are appropriate where, as here, the facts are complex in nature and narration would assist the trier of fact. See In re Yasmin & YAZ (Drospirenone) Mktg., Sales Pracs. & Prod. Liab. Litig., No. 3:09-MD-02100-DRH, 2011 WL 6302287, at *13 (S.D. Ill. Dec. 16, 2011). For example, in In Re: Tylenol, the court permitted the plaintiffs' marketing expert to provide a factual narrative related to actions taken by the defendants in developing the Tylenol brand, finding "narrative may be admissible if it involves complicated facts which the expert can help extrapolate for the jury." In Re: Tylenol, 2016 WL 807377, at *9 ("Dr. Goldberg's explanation of the actions undertaken by the defendants in creating the Tylenol brand is not simply a recitation of facts. He translates the meaning of those actions and what purpose they serve in branding."); see also In re Welding Fume Prod. Liab. Litig., No. 1:03-CV-17000, 2005 WL 1868046, at *17 (N.D. Ohio Aug. 8, 2005) ("It is through the application of his expertise that Dr. Levy may allow the trier of fact to better understand what the documents do (and don't) mean, and, thus, what the defendants did (or didn't) know."). There can be no denying that the factual underpinnings of this matter are complex, and as in In Re: Tylenol, the jury would be well served with an explanation regarding their significance.

In addition, JLI's "objection on th[is] basis is premature." *Focal Point Films, LLC v. Sandhu*, No. 19-CV-02898-JCS, 2020 WL 5760355, at *7 (N.D. Cal. Sept. 28, 2020) (denying motion to exclude testimony "solely for the purpose of constructing a factual narrative based upon record evidence") (internal citation and quotation marks omitted). As this Court has noted, there is "nothing that is *per se* improper in [an expert's] inclusion in her report of a detailed fact section explaining the basis of her opinions." *Id.* However, it is "improper for a *Daubert* motion and best raised as an objection at trial (should one be necessary)." *In re Glumetza Antitrust Litigation*, 2021 WL 3773621, at *20 (parenthetical in original). *See also Staub v. Breg, Inc.*, No. CV 10-02038-PHX-FJM, 2012 WL 1078335, at *3 (D. Ariz. Mar. 30, 2012) ("Objections to narrative testimony

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are best made at trial."); *In re Actos Prods. Liab. Litig.*, No. 12-cv-00064, 2014 WL 120973, at *10 (W.D. La. Jan. 10, 2014) ("The objection that testimony is 'narrative' is an objection as to form, foundation, or responsiveness, and must be presented at trial."); *In re Yasmin & YAZ Prods. Liab. Litig.*, MDL No. 2100, 2011 WL 6302287, at *8 (S.D. Ill. Dec. 16, 2011) (issues concerning narrative testimony should be "decided at trial in context specific situations"); *In re 3M Combat Arms Earplug Prod. Liab. Litig.*, 2021 WL 765019, at *41 ("The Court will not issue a 'blanket ban' on discussions of internal documents and declines to parse the experts' reports and depositions for statements that may cross the line into improper factual narration."). JLI's other cases are inapposite.

JLI generally relies on inapposite cases where the experts gave factual narratives disconnected from any opinion or where the experts lacked qualifications.⁵⁹ As detailed below, none of Plaintiffs' experts set forth a "factually unsupported narrative" concerning subject matter for which he or she "does not qualify as an expert." *Fujifilm Corp. v. Motorola Mobility LLC*, No. 12-CV-03587-WHO, 2015 WL 757575, at *26 (N.D. Cal. Feb. 20, 2015). Each expert presents relevant factual background that supports their opinions. *See United Food*, 296 F. Supp. 3d at 1194.

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probative"); Barber v. United Airlines, 17 F. App'x 433, 437 (7th Cir. 2001) (affirming exclusion

of expert who was unable to explain why he ignored certain facts while accepting others when he "did not give any additional data or information that he relied upon"); S.E.C. v. Tourre, 950 F.

Supp. 2d 666, 679 (S.D.N.Y. 2013) (disallowing mere narration disconnected from expert opinions where "[a]cting simply as a narrator of the facts does not convey opinions based on an expert's

knowledge and expertise").

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⁵⁹ See In re Trasylol Prod. Liab. Litig., 709 F. Supp. 2d 1323, 1346 (S.D. Fla. 2010) (excluding expert "because she ma[de] no effort to confine [her testimony] to her area of expertise" and used an unreliable methodology she "could not adequately explain"); Pooshs v. Phillip Morris USA, 287 F.R.D. 543, 547 (N.D. Cal. 2012) (excluding expert the court determined was "not qualified as an expert in researching document archives" after she was unable to explain how she conducted her searches and admitted to not having expertise related to their subject matter); Erhart v. BofI Holding, 445 F. Supp. 3d 831, 846 (S.D. Cal. 2020) (finding expert opinion that the "allegations are not supported by the evidence" to be "merely tell[ing] the jury what result to reach[,]" unfairly prejudicial, and needlessly cumulative); Andrews v. Metro N. Commuter R., 882 F.2d 705, 710 (2d Cir. 1989) (excluding testimony regarding legal standard of care by "an inexperienced layman posing as a railroad expert"); Waymo LLC v. Uber Techs., No. C 17-00939 WHA, 2017 WL 6887043, at *6 (N.D. Cal. Nov. 14, 2017) (excluding expert testimony that "add[ed] nothing by way of expertise," was "junk science," and was "substantially more prejudicial and misleading than

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1. Robert Proctor, Ph.D.

Dr. Proctor is a Professor of the History of Science at Stanford University. JLI Ex. 20, Proctor Rept. at 2. He has published extensively on the history of cancer, tobacco, and the health harms caused by cigarettes. *Id.* at 2-3. As courts have noted, "[h]e has qualified as an expert in numerous federal, state, and international courts, and Proctor's resume lists over a hundred instances in which he has qualified as an expert witness, as well as several pages of publications and books he has authored on related subjects." *Gerald v. R.J. Reynolds Tobacco Co.*, No. ST-10-CV-631, 2018 WL 4062154, at *9 (V.I. Super. Ct. June 12, 2018) (denying request to exclude Proctor's testimony). Courts have found him to be "eminently qualified to offer opinions on the history of the tobacco industry as reflected in industry documents." *Id.* "His work has been recognized through grants and fellowships from the National Institutes of Health, the National Science Foundation, the National Endowment for the Humanities and other prestigious organizations, he was a Fulbright Senior Fellow and a Fellow of the American Academy of Arts and Sciences, and was a Senior Scientific Reviewer for the 2014 Report of the United States Surgeon General on Smoking and Health." *Id.*

Of the many instances where Dr. Proctor has provided expert testimony as a tobacco historian, JLI never cited an instance where Dr. Proctor's testimony was excluded or limited for the reasons JLI offers in its motion. (JLI Mot. 4 at 5 (citing *Drake v. R.J. Reynolds Tobacco Co.*, 2015 WL 12746105, at *1 (S.D. Fla. Jan. 29, 2015) (permitting Proctor's testimony as to Defendants' present-day conduct and excluding only testimony related to litigation conduct and an ongoing conspiracy)). Amongst its irrelevant authorities, JLI misrepresents their holdings. In *Hubbird v. R. J. Reynolds Tobacco*, 2014 WL 5795298, *2 (Fla. Cir. Ct. Aug. 11, 2014), for example, the court granted a motion *in limine* to merely exclude evidence regarding the title of Dr. Proctor's book *Golden Holocaust*. In another, the court held that "Dr. Proctor may testify regarding tobacco industry documents and historical records to cigarette design, casual inference, and epidemiological studies," *In re: Engle Progeny Cases Tobacco Litigation*, No. 2008-CV-022558 (19), 2017 WL

8728335, at *1 (Fla. Cir. Ct. Apr. 17, 2017).⁶⁰

JLI's contentions focus on the pretense that tobacco history before JUUL's 2015 launch is irrelevant. (JLI Mot. 4 at 6). However, JUUL did not arise in a vacuum. Dr. Proctor explains that "[o]ne cannot understand the rise of Juul without understanding the broader history of nicotine and the tobacco industry." JLI Ex. 20, Proctor Rpt. at 3. JLI's development, production, and marketing of JUUL was directly inspired and influenced by the historical record regarding cigarette marketing. Indeed, JLI's co-founders have admitted, in public interviews, to having carefully studied the marketing strategies, advertisements, and product design revealed in cigarette industry documents in developing JUUL. 61 This history is relevant especially, as Dr. Proctor opines, because "Juul still today is using many of the same deceptive techniques used by Big Tobacco, including the recent purchase of an entire issue of a scientific journal to influence the science surrounding the hazards posed by Juul products." JLI Ex. 20, Proctor Rpt. at 5. "Historians are trained to recover 'facts' and, through selecting certain facts from the universe of available facts, construct narratives that explain a historical issue." United States v. Newmont USA, No. CV-05-020-JLQ, 2007 WL 4856859, at *3 (E.D. Wash. Nov. 16, 2007) (denying motion to exclude factual narrative). In his report, Dr. Proctor applies his expertise as a historian to "provid[e] historical context to the evidence." *Id*..⁶²

JLI also previews its forthcoming motion *in limine* to exclude reference to published authorities, "The Devil's Playbook" and "Big Vape." (JLI Mot. 4 at 7, FN 3). While Dr. Proctor

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⁶⁰ JLI's other case citations are distinguishable or refute its argument. *Hess v. Philip Morris USA*, 12/4/2008 Trial Tr. at 907-10, 923-24 (Fla. 17th Cir. Ct.) concerned racially charged language (not at issue here). In *Delancy v. R.J. Reynolds Tobacco*, No. 432008CA67, 2018 WL 11341743, at *5 (Fla. Cir. Ct. Sept. 12, 2018), the court restricted Dr. Proctor's testimony about an "ongoing conspiracy" but allowed him to "place company documents in historical context."

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⁶¹ See Plaintiffs' Amended Consolidated Master Complaint, Document 420, filed April 6, 2020, at p 55 (citing Gabriel Montoya, Pax Labs: Origins with James Monsees, Social Underground) available at https://socialunderground.com/2015/01/pax-ploom-origins-future-james-MONSEES/ (JLI co-founder James Monsees: "[Cigarette industry documents] became a very intriguing space for us to investigate because we had so much information that you wouldn't normally be able to get in most industries. And we were able to catch up, right, to a huge, huge industry in no time.").

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⁶² Contrary to JLI's argument, *Rezulin* is inapposite. In that case, the plaintiffs admitted that their expert lacked expertise to give a narrative of the regulatory history, and the expert admitted that "that he did not intend to give regulatory testimony" in any event. *In re Rezulin*, 309 F. Supp. 2d 531, 548-49 & n.56 (S.D.N.Y. 2004).

references these books, JLI Ex. 49, Proctor Dep. at 38:2-10, these are just two sources of dozens that Dr. Proctor relies upon. JLI Ex. 20, Proctor Rpt. at 115-17. Regardless, the Court should not now entertain JLI's yet-to-be-filed motion *in limine*. *See Burkhart v. R.J. Reynolds Tobacco*, No. 309CV10727WGYHTS, 2014 WL 12617550, at *8 (M.D. Fla. Apr. 30, 2014) (denying motion to categorically exclude Dr. Proctor's book "Golden Holocaust" as premature).

JLI further argues that Dr. Proctor did not review primary-source documents. However, much of the material Dr. Proctor reviews would constitute primary source materials, such as the JUUL adverts collected from Stanford University's Research into the Impact of Tobacco Advertising. *Id.* at 88-89. Moreover, JLI offers no authority to justify exclusion on this basis.

Instead, JLI provides two deposition excerpts to propose that Dr. Proctor's entire report is unsupported by any evidence. Based upon the first excerpt, JLI contends that Dr. Proctor did not specify the document repository to which he applied certain search terms, such as "destruction of documents." But this phrase appears in Dr. Proctor's discussion of how internal documents elucidating the "inner workings of the cigarette industry and cigarette design" have recently become available in a digital archive of formerly secret documents, and that because these tobacco documents have been run through an Optical Character Recognition tool, researchers can use search terms for easier access. *Id.* at 87-88. Both Dr. Proctor's deposition testimony and his report make clear that he is referring to the digital archive of documents pertaining to the cigarette industry. JLI uses the second excerpt to suggest that Dr. Proctor's failure to attribute the source of earlier surveys of underreported youth e-cigarette use to Juuling renders his entire report flawed. (JLI Mot. 4 at 8). Of course, in his report, Dr. Proctor elaborates on how CDC data indicated a decline in youth ecigarette use in June 2018, when "Juuling" was not included in the survey, and notes that the CDC did include the term in August 2018. JLI Ex. 20, Proctor Rpt. at 106. JLI may disagree on the significance of the inclusion of the term "Juuling" in surveying the full incidence of youth vaping, but exposing one missing footnote for a self-evident logical conclusion hardly justifies excluding Dr. Proctor's entire report.

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2. Robert Jackler, M.D.

Dr. Jackler's Report studiously details the factual record that supports his opinions consistent with the demands of Rule 26(a)(2)(B)(ii). JLI apparently believes—under the auspices of Daubert—that Dr. Jackler should not have tethered his opinions to any factual basis. JLI's argument is frivolous.

Dr. Jackler founded the Stanford Research into the Impact of Tobacco Advertising ("SRITA"), an interdisciplinary research group dedicated to study of the impact of tobacco advertising. JLI Ex. 11, Jackler Rpt. at 9. Tobacco industry marketing has been Dr. Jackler's primary field of research for over fifteen years. Id. JLI's contention that Dr. Jackler lacks the requisite experience to opine on the marketing of tobacco products by distorting his experience as a "personal hobby", (JLI Mot. 4 at 8), ignores the national recognition Dr. Jackler deservedly achieved. JLI Ex. 11, Jackler Rpt. at 10 (noting how SRITA's compendium of tobacco advertisements now resides at the Smithsonian Institution, where Dr. Jackler has given multiple public lectures on tobacco advertising). The United States Congress has recognized Dr. Jackler as "the preeminent tobacco advertising scholar in the country." As a scholar, Dr. Jackler relies in part on his fifteen years studying tobacco marketing targeting youths and the long history of companies doing just that. JLI Ex. 40, Jackler Dep. at 97:15-98:14. Dr. Jackler opines that JLI's branding, marketing, and advertising of JUUL attracted youth by adopting the same strategies that federal law prohibits manufacturers of combustible cigarettes from using for that reason. JLI Ex. 11, Jackler Rpt. at 19.

In contrast to JLI's preceding argument, JLI criticizes Dr. Jackler for including primary source examples of JUUL advertisements to support his opinion that JUUL advertisements had youth appeal. Id. at 12-13. To opine on such advertisements, Dr. Jackler's consideration of JLI's "various forms of marketing including, billboards, web advertising, email marketing, experiential marketing, sampling, and point of sale advertising," is fundamentally sound.

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3. John Chandler, Ph.D.

Dr. John Chandler is a Clinical Professor of Marketing at the University of Montana with over twenty-two years' experience as a marketing practitioner. JLI Ex. 3, Chandler Rpt. at 3. His primary focus has been on digital marketing with a secondary focus on television advertising. *Id.* JLI's breezy characterization of sixty-five pages of Dr. Chandler's report as "nothing more than fact narration," (JLI Mot. 4 at 9), is divorced from the actual report which is replete with substantiated analysis and opinions. *See, e.g.*, JLI Ex. 3, Chandler Rpt. at 9 (opining on what effect an experienced marketer would have expected with regard to JUUL marketing strategies); *see Id.* at 11, 12, 13, etc.

JLI argues that Dr. Chandler's methodology is unreliable because he did not do a "comprehensive study" of any of the separate topics addressed in his report, (JLI Mot. 5 at 9-10), but offers no authority to support any requirement for such a showing. And JLI glosses over Dr. Chandler's discussion of JUUL advertising campaigns and media strategies and conclusion that an experienced marketer would have expected JLI to have performed based on those results. JLI Ex. 3, Chandler Rpt. at 9. Dr. Chandler employed the marketing analytics JLI contends is lacking. For example, how JLI used influencers to make JUUL appeal to the "cool kids[,]" which he breaks down into the relevant time periods, see, e.g., id., with specific reference to the anticipated impact of certain individual influencers. See, e.g., id. at 25 (concerning YouTube Influencer Bryan Simon); id. at 30-31 (Katy Perry). In assessing JLI's general influencer strategy, he examined the most successful campaigns that had reached the largest audience. See JLI Ex. 32, Chandler Dep. at 221:7-14. JLI may argue that the inclusion of some older influencers with an older following adds to the total audience reached, but that misses the point of Dr. Chandler's conclusions concerning the success of the influencer program in reaching youth markets. The total effect of JLI's advertising campaign would capture each campaign strategy (even if there were additional aspects that were only partially youth-appealing or even if they had no youth appeal). As he explained at deposition with regard to his review of JLI's influencer program:

I was really focused on the influencers who I thought best answered the questions around to what extent JUUL's marketing strategies reach[ed] youth. And so the fact that they also reached non-youth is interesting, but it doesn't change the reach to

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youth. You can't reach a 65-year-old and undo the reach to a 15-year-old.

Id. at 250:20-251:4 (edits for clarification). Dr. Chandler's report focuses, necessarily, on the most salient (and successful) features of JUUL marketing efforts that reached youth markets. JLI's superficial argument that Dr. Chandler "cherry-picked" facts demonstrates precisely why courts adhere to the principle that "vigorous cross-examination" is the traditional and preferred method to address expert witnesses, not exclusion of testimony. *Daubert*, 509 U.S. at 596.

4. <u>Samuel Woolley, Ph.D.</u>

Dr. Woolley is an assistant professor of journalism and media at the University of Texas at Austin and head of the Propaganda Research lab at UT. JLI Ex. 29 at 1. He has spent the last ten years studying how digital media is used to influence human behavior. *Id.* at 1-4. Dr. Woolley opines on JUUL's use of online and offline information manipulation strategies and those efforts' focus on targeting young potential consumers. *Id.* at 5.

JLI argues that Dr. Woolley provides only a narrative summary of record evidence, and that some of this narration (specifically that concerning JLI-funded research studies) falls outside of Dr. Woolley's area of expertise. (JLI Mot. 4 at 10-11). Dr. Woolley's factual discussion of JLI's social media presence and marketing strategies provide the context for his opinions on those digital campaigns, which is informed by his expertise in how digital media can influence consumer behavior. JLI Ex. 29, Woolley Rpt. at 17 (concerning the social media strategy of using fake social media followers to manufacture consensus); *id* at 40 (discussing the relationship between "owned" and "earned" media and social media campaigns to amplify user-generated content).

JLI misrepresents Dr. Woolley's report to argue that JLI's scientific research is irrelevant to his conclusions and outside his area of expertise. But industry-funded studies (historically used by big tobacco) are an example of information manipulation through the weaponization of "science." *Id.* at 56. Citing to the academic literature on the subject, Dr. Woolley acknowledges the widely recognized relationship between such industry funding and results favorable to the source of that funding. *Id.* at 51-52. Dr. Woolley notes the funding connections between various groups like the Centre for Substance Use Research ("CSUR") and JLI, and the results of JLI-sponsored research. *Id.* at 51-54. And yet JLI takes issue with Dr. Wooley's recitation of the facts or data he

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considered, which is consistent with the requirements of Rule 26(a)(2)(B)(ii). Dr. Woolley references an article discussing the methodological limitations of CSUR research in his broader discussion and analysis of JLI's use of JLI-funded studies in its public messaging. *Id.* at 67. *See Vazquez v. City of New York*, No. 10-CV-6277 JMF, 2014 WL 4388497, at *12 (S.D.N.Y. Sept. 5, 2014) (admitting expert opinion based in part on "review of academic literature of a type reasonably relied upon by experts in various disciplines of social science.") (internal quotation marks omitted); *see also Wendell v. GlaxoSmithKline LLC*, 858 F.3d 1227, 1235 (9th Cir. 2017). *Cf. Exxon Shipping Co. v. Baker*, 554 U.S. 471, 128 S.Ct. 2605, 2626 n. 17 (2008) (declining to rely on research even partially funded by the defendant).

5. Neil E. Grunberg, Ph.D.

Dr. Grunberg specializes in tobacco, nicotine addiction, and behavioral health and has advised the Department of Defense, the National Institutes of Health, and Food and Drug Administration. JLI Ex. 8, Grunberg Rpt. at 1. *See Mash v. Brown & Williamson Tobacco*, No. 4:03CV0485TCM, 2004 WL 5537079, at *3 (E.D. Mo. Aug. 2, 2004) ("Dr. Grunberg's career has apparently been focused on the dangers and dependence of cigarette smoking."). As courts have recognized, "Dr. Grunberg is a trained social psychologist who studies tobacco use and addiction, and possesses expertise on the social forces that influence a smoke's tobacco use." *Dover v. R.J. Reynolds Tobacco*, No. 3:09-CV-11531 SAS, 2014 WL 4723116, at *6 (M.D. Fla. Sept. 22, 2014). *See also* JLI Ex. 8, Grunberg Rpt. at 4 (listing expert qualifications including a Ph.D. in Psychology (Social and Physiological Psychology) from Columbia University).

JLI claims that he opines on topics, like marketing, outside his expertise. When presented similar *Daubert* challenges, courts have found that after "careful review of Dr. Grunberg's education, professional qualifications, and professional work, [...] he is qualified to testify concerning cigarette advertising and marketing." *Id.* JLI nevertheless argues that Dr. Grunberg does not "systematically review company documents in his published research[.]" (JLI Mot. 4 at 11). While JLI does not develop its argument, courts have found that Dr. Grunberg is qualified to review company documents and offer an opinion accordingly. *See Berger v. Philip Morris USA*, No. 309CV14157WGYHTS, 2014 WL 10715266, at *4 (M.D. Fla. Aug. 29, 2014) (holding that

"Dr. Grunberg may rely on his qualifications to testify on internal company documents, opinions on cigarette design, and cigarette advertising and marketing."). Further, JLI's attack on Dr. Grunberg's methodology —based not on any challenge to his list of documents he relied on, but on the fact that he read all of the documents he was provided—is equally undeveloped and meritless. JLI Ex. 37, Grunberg Dep. at 193:3-8. *See Jensen v. American Medical Systems*, 2021 WL 6139631, at *5 (E.D. Wash. Apr. 30, 2021) (expert's methodology reliable where "he has reviewed deposition materials; [...] medical records; scientific literature; [and] corporate documents from Defendant [...] in forming his opinions.").

6. Sharon Levy, M.D., M.P.H.

Dr. Levy is a pediatrician, board certified in Developmental Behavioral Pediatrics and Addiction Medicine, and an Associate Professor of Pediatrics at Harvard Medical School. JLI Ex. 13, Levy Rpt. at 1. She offers opinions on the impact of e-cigarettes generally, and specifically addresses JUUL's effect on the health of children, teenagers and young adults. *Id.* at 6. She discusses the success of the JUUL marketing campaign and the subsequent unprecedented influx of new, increasingly younger patients to her clinic with nicotine use disorders. *Id.* at 37. JLI objects to Dr. Levy's discussion of JUUL marketing in relation to its effect on adolescents, but her opinions on how various JUUL design features and marketing campaigns were attractive to adolescents fit squarely within her expertise in behavioral pediatrics and personal observations in her clinical practice.

JLI also mischaracterizes her testimony. While the excerpted testimony concerns only her diagnostic formulation for Plaintiff B.B. and is a separate expert report from the one JLI is challenging here, Dr. Levy explained that every patient evaluation is different. JLI Ex. 42, Levy Dep. at 65:11-13. Given the circumstances of Dr. Levy's consultation with Plaintiff B.B. (occurring as a result of Dr. Levy's involvement in a lawsuit), there were parts that would have been specific to B.B.'s legal case. *Id.* at 64:6-65:13. Dr. Levy was equally clear that her expert diagnostic formulation was medical and not legal in nature. *Id.* at 65:14-66:8. JLI again makes passing reference to a lack of "reliable methods" without providing any substantive analysis of Dr. Levy's methodology or reliance materials. *See* JLI Ex. 13, Levy Rpt. at 6-7 (outlining methodology);

Exhibit B (identifying materials considered). This Court should reject JLI's undeveloped arguments.

7. Kurt M. Ribisl, Ph.D.

Dr. Ribisl is the Jo Anne Earp Distinguished Professor and Chair in the Department of Health Behavior at the Gillings School of Global Public Health at the University of North Carolina at Chapel Hill. JLI Ex. 22, Ribisl Rpt. at 2. He has over twenty-five years of experience in tobacco control policy research. *Id.* His primary research area has been in tobacco regulatory science with a focus on sales and marketing of tobacco products at retail and online vendors. *Id.* Dr. Ribisl's Congressional briefing on his research work into online sales of tobacco products to minors and online age verification requirements helped lead to the passage of the 2009 Prevent All Cigarette Trafficking Act. *Id.* at 2-3.

Contrary to JLI's contention, JLI's youth prevention and age verification efforts are squarely within the purview of Dr. Ribisl's expertise related to age and identity verification of minor purchasers of tobacco products. (JLI Mot. 4 at 12); JLI Ex. 22, Ribisl Rpt. at 2-3. Dr. Ribisl's review of internal corporate documents and deposition testimony forms the basis for his opinion that JLI failed to take available steps to prevent youth from getting access to JUUL products, which led or strongly contributed to the epidemic of JUUL use among youth. *Id.* at 4-7. While it is unclear which portions of Dr. Ribisl's report JLI seeks to exclude, his disclosure of the materials reviewed and analysis which incorporates his conclusions relating to and drawing from his experience are consistent with Rule 26(a)(2)(B)(ii). *See e.g.*, *id.* at 10 (opining on JLI's failure to implement adequate safeguards to prevent youth purchases); *see also id.* at 16; 35; etc.).

JLI's glancing argument that Dr. Ribisl did not implement a systematic methodology omits any supporting analysis or argument. (JLI Mot. 4 at 12). Dr. Ribisl reviewed, *inter alia*, deposition testimony, exhibits, and scientific literature, whose comprehensiveness JLI fails to mount any substantive challenge. JLI Ex. 22, Ribisl Rpt. at 3. *See, e.g., Staub v. Breg, Inc.*, No. CV 10-02038-PHX-FJM, 2012 WL 1078335, at *3 (D. Ariz. Mar. 30, 2012) (finding expert testimony to be reliable where the methodology involved a review of "FDA regulations and publications, medical literature, depositions, defendant's internal communications, and correspondence with the FDA [...

and the expert] la[id] a foundation for her opinions based on these documents and links her analysis to her opinions."). JLI's arguments are unfounded and meritless.

8. Eric Lindblom, J.D.

Equally unfounded is JLI's challenges to Mr. Lindblom's expert testimony as either irrelevant, misleading, unduly narrative, and/or biased. JLI boxes all its arguments into one paragraph. (JLI Mot. 4 at 12). This Court should reject all JLI's arguments as both undeveloped and substantively baseless.

Mr. Lindblom is a renowned authority on legal and policy matters related to tobacco products and their regulation. JLI Ex. 15, Lindblom Rpt. at 2. He previously served as Director of the Office of Policy at FDA's Center for Tobacco Products and has published papers on how, based on his experience, e-cigarette manufacturers could design, market, and sell their products in ways to minimize public harm. *Id.* at 5. JLI contends that its development and marketing of JUUL "has no relevance" to Mr. Lindblom's evaluation of the legal standard designing and marketing e-cigarettes against the regulatory backdrop governing tobacco products. (JLI later argues that the TCA provides the only applicable standard to JLI products.) (JLI Mot. 4 at 27). Regardless, Mr. Lindblom's review of tobacco control laws and regulations provides the background to his conclusions related to the lack of comprehensive framework of tobacco control laws governing JLI products. JLI Ex. 15, Lindblom Rpt. at 7.

JLI does not challenge Mr. Lindblom's qualifications to offer his opinions. Instead, JLI just criticizes Mr. Lindblom's discussion of JUUL's marketing outreach, which was necessary to contextualize his conclusions about what could have been done given the regulatory framework. (JLI Mot. 4 at 12). Absent any well-articulated challenge to Mr. Lindblom's methodology, JLI's misguided quip regarding the breadth of material Mr. Lindblom requested and reviewed is nothing more than fodder for cross examination.⁶⁴

⁶⁴ See JLI Ex. 44, Lindblom Dep. at 24:6-22 ("I asked always for information about certain topics, and so I was always given the information I was asked for, whether it was depositions or exhibits, and then I looked at them very carefully. And most of what I looked at were things that people from JUUL said in their depositions, or exhibits, documents from JUUL. So I'm not sure what else I could have asked for. . . . I asked for anything and everything that related to marketing the product.") (edited for clarity).

B. This Court Should Deny JLI's Motion to Exclude So-Called State-of-Mind Opinions.

JLI believes that experts are categorically barred from reviewing individual or corporate communications and then reaching a conclusion about what information an individual or corporation knew or should have known based off of those communications. JLI's argument is frivolous. Under Federal Rule of Evidence 704(a), "An opinion is not objectionable just because it embraces an ultimate issue." Notably, Rule 704(b) expressly bars experts from giving state-of-mind opinions in *criminal* cases. JLI effectively asks this Court to modify the text of 704(b), and to hold—contrary to the express language of Rule 704(b)—that no expert in *any* case can testify to what an individual or corporations knew or should have known. This Court should reject JLI's argument because Rule 704(b) limits any categorical restriction on intent opinions to criminal cases, not civil actions.

1. This Issue Should be Resolved at Trial, if at all.

Initially, JLI's argument is not a proper *Daubert* challenge. JLI believes that state-of-mind opinions are *per se* speculative, but "any alleged speculation within [these experts'] report[s] is not properly the subject of this *Daubert* analysis and should be addressed to the Court in the context of the presentation of evidence at trial." *DePuy Orthopaedics*, 2016 WL 6271474 at *4. Moreover, JLI has provided little, if any, context for the statements it seeks to exclude, and "the admissibility of a particular statement or opinion is dependent on the context in which it is offered and the foundation on which it is based." *National Prescription Opiate Litig.*, 2019 WL 4165021, at *3; *Xarelto*, 2017 WL 1352860, at *2.

2. Plaintiffs' Experts did not Render Speculative State-of-Mind Opinions.

As previously noted, JLI's argument is legally incorrect. In fact, the Ninth Circuit has explicitly rejected the argument that experts cannot testify to a party's state of mind:

Vaughn and Castle Rock contend that the district court improperly allowed Huson's law enforcement expert to testify that Vaughn recklessly and intentionally disregarded professional standards in conducting his investigation of the theft.

This argument is without merit. ... Rule 704 permits expert opinion testimony on such ultimate issues. Moreover, Rule 702 permits

expert o	pinion testimony	comparing the	conduct of the	parties to the
	standard.	1 0		•

Huson v. City of Castle Rock, 9 F.3d 1551 (9th Cir. 1993) (table) (unpublished). See also Davis v. Mason County, 927 F.2d 1473, 1484–85 (9th Cir. 1991) (expert can testify that defendant acted recklessly); Hangarter v. Provident Life & Accident Ins., 373 F.3d 998, 1017 (9th Cir. 2004) (expert can testify that defendant acted in bad faith).

Similarly, this Court held in Cover that an expert can testify to what a defendant "knew or should have known" because "[a]n expert may testify to an ultimate issue of fact if that testimony would assist the trier of fact." *Cover v. Windsor Surry Co.*, No. 14-CV-05262-WHO, 2017 WL 9837932, at *17 (N.D. Cal. July 24, 2017) (Judge Orrick) (citing Fed. R. Evid. 704(a) ("An opinion is not objectionable just because it embraces an ultimate issue.")). *Vallecillo v. McDermott, Inc.*, No. 6:19-CV-00508, 2021 WL 5983186, at *4 (W.D. La. Dec. 17, 2021) (holding that expert can testify to what defendant "knew or should have known"); *Dahlstrand v. FCA US, LLC*, No. 15 CV 7603, 2021 WL 4318322, at *3 (N.D. Ill. Jan. 14, 2021) (holding that expert can testify to what plaintiff "knew or should have known"). Notably, Federal Rule of Evidence 704(b) explicitly bars experts from giving state of mind opinions in *criminal* cases, but "this is a *civil* case." *Dahlstrand*, 2021 WL 4318322, at *3 (emphasis added).

Moreover, JLI seeks to exclude opinions that do not go "to motive or intent." *In re E.I. du Pont de Nemours & Co. C-8 Personal Injury Litig.*, 348 F. Supp. 3d 698, 719 (S.D. Ohio 2016). Rather, Plaintiffs' experts "offer[] opinions from the application of [their] expertise to documents and their contents, not speculation as to [JLI's] state of mind." *In re DePuy Orthopaedics, Inc. Pinnacle Hip Implant Prod. Liab. Litig.*, No. 3:11-MD-2244-K, 2016 WL 9560113, at *7 (N.D. Tex. Oct. 3, 2016). These opinions of "what the defendants knew about risks [...] based on internal documents or depositions by defense witnesses [they] reviewed [...] are not based on speculation

⁶⁵ Holding that "[t]he Court disagrees [...] with DuPont's contention that Dr. Redlich speculates as to DuPont's motive and intent when she opines on what DuPont knew or should have known. Dr. Redlich reviews a complicated historical record and, based upon her unique qualifications, opines on what she believes DuPont knew or should have known at given points in time. This is not testimony that goes to motive or intent.

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or inference." See In re Tylenol Mktg Sales Practices & Prod. Liab. Litig., 2016 WL 4039329, at *6 (E.D. Pa. July 28, 2016). Each "expert adequately demonstrates a basis for an opinion about what the defendants knew or should have known from such information that was within the defendants' possession," so each "opinion may be admissible at trial, if the proper foundation is laid." Shults v. Int'l Flavors & Fragrances, 2014 WL 12603223, at *3 (N.D. Iowa July 18, 2014).

Through the prism of their disciplines, Plaintiffs' experts properly explain the content of JLI's communications and what those documents "reflect in connection with relevant issues in this case." Jacobson v. R.J. Reynolds Tobacco, 2013 WL 12094860, at *2 (S.D. Fla. Sept. 20, 2013) (holding that "Dr. Proctor may testify about these documents [...] and what they reflect in connection with relevant issues in this case" including "Defendants' evolving knowledge of [...] the addictive properties of nicotine and the health risks that came to be associated with smoking"). For example, in In re DePuy Orthopaedics, Inc. Pinnacle Hip Implant Prod. Liab. Litig., the court held that an expert may apply "specialized knowledge in the discipline of marketing, including the areas of marketing codes, regulations, and guidelines, to analyze voluminous specific marketing representations made by Defendants, and this testimony is helpful to the factfinder" because this would be an "application of [...] expertise to documents and their contents, not speculation as to [Defendant's] state of mind." 2016 WL 9560113, at *7. Additionally, in In re E.I. du Pont de Nemours and Company C-8 Personal Injury Litig., the court disagreed "with DuPont's contention that Dr. Redlich speculates as to DuPont's motive and intent when she opines on what DuPont knew or should have known. Dr. Redlich reviews a complicated historical record and, based upon her unique qualifications, opines on what she believes DuPont knew or should have known at given points in time. This is not testimony that goes to motive or intent." 348 F. Supp. 3d at 719. Here, Plaintiffs' experts use their specialized knowledge in tobacco marketing, design, and addiction to analyze documents demonstrating JLI's actions and representations in the dangerous design and marketing of JUUL products, particularly to youth.

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JLI largely relies on cases that are inapposite⁶⁶ or refute its argument.⁶⁷ To the extent JLI cites any cases that appear to support a blanket prohibition on so-called state-of-mind opinions, this Court is bound by controlling precedent. *See Davis*, 927 F.2d at 1484–85 (expert can testify that defendant acted recklessly); *Hangarter*, 373 F.3d at 1017 (expert can testify that defendant acted in bad faith); *Huson*, 9 F.3d 1551 (expert can testify that defendant acted intentionally and recklessly). Moreover, the permissive approach is more consistent with the text of Rule 704.

Periodically, JLI argues that a particular Plaintiffs' expert does not have "special expertise in corporate intent." (JLI Mot. 4 at 15-20). However, Plaintiffs' experts do not need expertise in corporate intent or governance to render opinions on what JLI's internal communications indicate. As explained below, each expert is highly qualified to discuss JUUL's design, marketing, or health effects related to youth use of the product and may testify about what JLI "knew or did not know" when that knowledge is demonstrated in the record. *See Tylenol*, 2016 WL 4039329, at *6 (holding that "what the defendants knew about risks of acetaminophen-induced liver failure based on internal documents or depositions by defense witnesses she reviewed [...] are not based on speculation or inference").

a. <u>Dr. Minette Drumwright.</u>

JLI incorrectly highlights five phrases from Dr. Drumwright's report as "classic state-of-mind opinions." (JLI Mot. 4 at 15). However, JLI does not argue that Dr. Drumwright lacks factual support for *any* of these opinions. Moreover, the context surrounding each of these phrases shows that Dr. Drumwright is not "try[ing] to interpret [JLI's] intentions." JLI Ex. 34, Drumwright Dep.

⁶⁶ See e.g., In re Guidant Corp. Implantable Defibrillators Prods. Liab. Litig., 2007 WL 1964337, at *7-8 (D. Minn. June 29, 2007) (finding that "[t]here is no foundation for such opinion testimony" and "such testimony is not based upon sufficient facts or data"); Snyder v. Bank of Am., N.A., 2020 WL 6462400, at *2 (N.D. Cal. Nov. 3, 2020) (excluding testimony from someone the court had previously found was "not an expert on this matter."); In re Bard IVC Filters Prod. Liab. Litig., 2017 WL 6523833, at *3 (D. Ariz. Dec. 21, 2017) (excluding expert who gives opinion outside area of expertise that is not connected to facts).

⁶⁷ See Hill v. Novartis Pharm., 2012 WL 5451816, at *2 (E.D. Cal. Nov. 7, 2012) (holding that "Dr. Marx is not precluded from [...] offering expert opinions about the information available to Defendant internally and from relevant medical literature [...]"); Georges v. Novartis Pharms. Corp., 2013 WL 5217198, at *15 (C.D. Cal. Apr. 4, 2013) ("To the extent the information on the known risks is derived from internal Novartis documents, Dr. Vogel's scientific expertise is helpful to the trier of fact in understanding those documents [...]") (quoting Deutsch v. Novartis Pharms., 768 F. Supp. 2d 420, 443 (E.D.N.Y.2011)).

at 15:22. Rather, she is offering "opinions from the application of her expertise to documents and their contents." *In re DePuy Orthopaedics, Inc. Pinnacle Hip Implant Prod. Liab. Litig.*, 2016 WL 9560113, at *7 (rejecting motion to exclude Dr. Drumwright's testimony on similar grounds, finding that she "has applied her specialized knowledge in the discipline of marketing, including the areas of marketing codes, regulations, and guidelines, to analyze the voluminous specific marketing representations made by Defendants, and this testimony is helpful to the factfinder"). Particularly, the quotes cited in JLI's Motion from pages 52, 54, 85, and 86 of Dr. Drumwright's report are matters relevant to her opinions made within her discipline, which includes discussions about JUUL's violations of various marketing codes and standards. Dr. Drumwright properly relies upon deposition testimony, e-mails, and internal JLL documents.

b. <u>Dr. Bonnie Halpern-Felsher.</u>

c. <u>Dr. Robert Jackler.</u>

appropriately based on the evidentiary record.

JLI finds fault with several headings within Dr. Jackler's report, but JLI does not question the factual basis for these opinions. For example, the heading "Before its Launch, JUUL Leadership was Aware that Their Product Had the Potential to Appeal to Youth" is supported by record evidence

1	JLI Ex. 11, Jackler Rpt. at 32
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3	Further, JLI ignores context surrounding the two Dr. Jackler report passages it questions.
4	("See, e.g., id. at 112 (JLI 'knew the product would be very attractive to youth'); id. at 27 ('JUUL
5	was cognizant that it needed to make an emotional connection in its advertising to be
6	successful."")).
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8	<i>Id.</i> at 112.
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10	<i>Id.</i> at
11	27 (citing Mumby dep. starting at 204). Dr. Jackler's statements are descriptions of record evidence
12	based on his specialized tobacco-industry marketing knowledge, not unsupported speculation.

d. Dr. Anthony Pratkanis.

JLI argues that Dr. Pratkanis's opinion is "a cursory review of JLI internal documents and his own say-so." (JLI Mot. 4 at 16) But Dr. Pratkanis has over 35 years of experience as an expert in social influence, persuasion, and consumer behavior, and he carefully reviewed an extensive amount of materials before writing his report. Taking extreme license, JLI also claims that Dr. Pratkanis rendered an opinion "without any empirical analysis," id., yet Dr. Pratkanis "employed a social influence analysis" "to review and assess JLI's marketing communications," which consisted of a review of "relevant marketing communications (in this case, JLI's ads, social medical communications, public relations (PR), events, and other marketing communications)" before applying general concepts and principles of consumer behavior being invoked in the JUUL communications. JLI Ex. 17, Pratkanis Rpt. at 4. In doing this, Dr. Pratkanis utilized the concepts and principles outlined in numerous references, as outlined in Appendices D-F of his report. Id. Other courts have utilized this method. See State v. LA Investors, LLC, 410 P.3d 1183, 1192 (Wash. Ct. App. Feb. 13, 2018). JLI protests only one of Dr. Pratkanis's opinions – a summary statement from Dr. Pratkanis's list of general conclusions. Again, this Court should reject JLI's motion

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because it does not challenge the factual basis for Dr. Pratkanis's opinion or the methodology he used to reach his conclusions.

e. <u>Dr. John Chandler.</u>

Dr. John Chandler is an expert in the analytics and data science of digital marketing and television advertising. JLI Ex. 3, Chandler Rpt. at 3. In the span of his career, he has conducted numerous advertising research projects, including one study in which billions of ad impressions were analyzed "uncovering the relationship between the audience the advertiser was targeting and that audience's position in the conversion process." *Id.* This experience and knowledge informed Dr. Chandler's opinions. Yet, JLI claims that Dr. Chandler applied no "expertise or any reliable methodology" (JLI Mot. 4 at 17). to his opinions. Since Dr. Chandler used his extensive research and work experience of analyzing marketing and advertising data for companies such as Microsoft, LinkedIn, General Mills, Expedia, and Nike, JLI Ex. 3, Chandler Rpt. at 4, to methodically outline his analysis of JUUL's marketing strategies that would target youth and the pervasiveness of JUUL's social media marketing strategies to youth markets. *Id.* at 7. JLI's arguments are unfounded, inaccurate and misguided.

JLI disputes just one statement from Dr. Chandler's report that "JUUL intended for its marketing to extensively advertise to markets that included significant numbers of youth consumers and media consumers." *Id.* at 8. Significantly, JLI does not question the veracity of this fact. JLI cites to Dr. Chandler's deposition, but that only demonstrates that his opinion is well-founded:

There are a number of documents where JUUL lays out a marketing strategy, and I believe these are all footnoted, so we could sort of go through them. . . .

And so, you know, the word "intended" there is really saying that JUUL had a marketing strategy that, if they weren't selling a nicotine delivery system, would be a very standard sort of playbook for encouraging viral spread and having a very successful product launch and continued marketing of that product.

JLI Ex. 32, Chandler Dep. at 85:9-12; 85:20-25 – 86:2-7. Dr. Chandler also utilized his marketing expertise to reach this conclusion:

... I am not sure if somebody who wasn't familiar with marketing would necessarily see it through the same lens. You know, I can see, oh, we are going to engage heavily on social media and we are going

to make extensive use of hashtags, and then later we are going to encourage and embrace full event – like TikTok utilization, those kind of things. Some of that came out of the documents, some of that came out of kind of my marketing experience and how I would expect marketers to use these kinds of tools, and how I would expect experienced marketers, which it seemed like JUUL had.

Id. at 87:14-88:4. Because Dr. Chandler reached a reliable opinion based upon his expertise and the record, this Court should deny JLI's motion.

f. Dr. Samuel Woolley.

Dr. Woolley extensively analyzed documents, online data, and testimony about JUUL's information manipulation campaign before rendering his opinions. JLI Ex. 29, Woolley Rpt. at 5. JLI argues that Woolley's analysis is "one-sided" and "strongly disagrees" with the conclusions he reaches. (JLI Mot. 4 at 17). As JLI notes, Dr. Woolley based his opinion on "JLI personnel statements, documents, and emails," and drew inferences using his expertise. *Daubert* motions are not the proper mechanism to challenge experts' conclusions. That evaluation is to be conducted by the trier of fact, *i.e.*, the jury. This Court should therefore deny JLI's motion.

g. <u>Dr. Sharon Levy.</u>

JLI alleges that Dr. Levy lacks specialized knowledge or expertise in corporate governance to opine about JLI's awareness of youth targeting within its marketing and ad campaigns. (JLI Mot. 4 at 18). But Dr. Levy is more than qualified to opine on the addictive nature of JUUL and JLI's actions that made the product particularly appealing to youth. Dr. Levy is an adolescent addiction expert who has spent the last twenty years evaluating and treating youth with substance use problems and disorders. JLI Ex. 13, Levy Rpt. at 5. Her extensive research in this field has led to the development of screening tools and intervention strategies to address adolescent substance use. *Id.*

Consequently, JLI does not challenge the factual basis for Dr. Levy's opinions, which included analysis of internal JLI documents. (JLI Mot. 4 at 18). JLI simply disagrees with the inferences and conclusions Dr. Levy draws from the evidence. That, however, is not an appropriate basis to exclude expert testimony. The motion should be denied.

h. Dr. Neil Grunberg.

Dr. Grunberg is a professor and clinical psychologist who has conducted extensive research and publishing in the areas of nicotine and tobacco use and addiction. JLI Ex. 8, Grunberg Rpt. at 4-10. He has consulted with numerous government entities, including Department of Defense, National Institutes of Health, and Food and Drug Administration, on nicotine addiction, tobacco use, and behavioral health. *Id.* at 1. Contrary to JLI's argument, Dr. Grunberg does not need to also be an expert in corporate governance to opine to matters that are well within his discipline. As Dr. Grunberg explains – and JLI points out – his opinions are "[b]ased on the documents I have reviewed" and his knowledge of "the expertise of those involved in formulating JLI's product." *Id.* at 25. JLI does not dispute the factual basis for Dr. Grunberg's opinions. Notably, courts have permitted Dr. Grunberg to give similar opinions. *See Berger v. Philip Morris USA*, 2014 WL 10715266, *4 (M.D. Fla. Aug. 29, 2014); *Kerrivan v. R.J. Reynolds Tobacco*, 2014 WL 12623812, at *2 (M.D. Fla. Sept. 30, 2014).

i. <u>Dr. Judith Prochaska.</u>

Incredibly, JLI challenges the ability of Dr. Prochaska to render her opinions as an expert in nicotine addiction. She is a member of Stanford's Research into the Impact of Tobacco Advertising (SRITA), which studies the effects of tobacco advertising, marketing, and promotion, and she has conducted multiple research studies on the effects of tobacco product marketing and policies. JLI Ex. 18, Prochaska Rpt. at 1-2. JLI's attempt to pigeon-hole her expertise to combustible cigarettes is risible since the addictive harm of all these products derive from nicotine in tobacco. After that, all that remains of JLI's argument, are disputes involving the inferences and conclusions she draws from JLI's evidence. That is an improper application of *Daubert*, which should not be endorsed.

j. Eric Lindblom.

JLI disputes Mr. Lindblom's qualifications as well, but he is an expert on legal and policy matters related to tobacco products and their regulation. He has worked in the tobacco industry for over twenty years, having served as Director for Tobacco Control and Food & Drug Law at Georgetown Law's O'Neill Institute for National & Global Health Law, Director of the Office of

Policy at FDA's Center for Tobacco Products, and General Counsel and Director for Policy Research at the Campaign for Tobacco-Free Kids. JLI Ex. 15, Lindblom Rpt. at 2. Mr. Lindblom specializes in the interplay between tobacco products, the regulations that control them, and their related health concerns. *Id*.

Like its other arguments, JLI challenges so-called state-of-mind opinions but does not question the factual basis for those opinions. (JLI Mot. 4 at 20). Mr. Lindblom's specialized knowledge about the legal and policy implications of JLI's actions is at the heart of his opinions, enables him to better evaluate JLI's documents, which cannot be replicated by a typical juror.

JLI Ex. 15, Lindblom Rpt. at 75. This statement is within a section in which Mr. Lindblom analyzes JUUL's marketing actions towards youth within the context of the Final Deeming Rule and JUUL's Marketing Code, topics not generally known to a lay person. *Id.* at 73-77. This Court should not exclude Mr. Lindblom's opinions, which "will help the jury understand how the defendants' actions may have fallen short of the duties required of them." *See In re Tylenol Mktg Sales Practices & Prod. Liab. Litig.*, 2016 WL 4039329, at *6.

k. Dr. David Cutler.

JLI disputes two quotes from Dr. Cutler's Report attributing JUUL's knowledge of the product's marketing and design appeal to youth. Dr. Cutler's analysis is taken from a discussion of information gathered from JUUL's Social Media Manager. The full statement reads:

JUUL clearly knew its product had strong appeal to youth and that its marketing had strong youth appeal. For example, according to JUUL's Social Media Manager, Nora Walker,

JLI Ex. 4, Cutler Rpt. at 99-100. Dr. Cutler's opinions are not speculation – they are grounded in the testimony of a JUUL employee and internal documents. Indeed, JLI does not question the factual basis for these opinions.

JLI also conclusory argues that Dr. Cutler's opinions are "not based on any reliable methodology." (JLI Mot. 4 at 20). But Dr. Cutler's methodology is fully described in his report and the same methodology has been confirmed in other litigations. *See, e.g., In re: National Prescription Opiate Litigation*, 2019 WL 4011729, at *4 (N.D. Ohio Aug. 26, 2019) ("Cutler's report is a model of transparency, explaining every choice he made in designing his analysis. There, and in deposition testimony, Cutler explained the strengths *and* weaknesses of his choices, and the consequences of its flaws."). This Court should similarly permit Dr. Cutler to give his opinions about what JLI knew based upon JLI's own internal communications.

1. <u>Dr. Thomas Eissenberg.</u>

JLI selectively quotes Dr. Eissenberg's report to accuse him of speculating about JLI's knowledge. (JLI Mot. 4 at 21). However, JLI fails to provide any context that dispels the notion. For example, JLI challenges Dr. Eissenberg for stating, "JLI was aware of [...] the need for a 'lockout' option," but excludes the remainder of the paragraph, which provides the context JLI contends is missing:

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Draft Invention Disclosure Form, JLI42421320-25; Connected Device Idea Summary Email Chain and Attachment, JLI02246757-65).

(JLI42421320-25; JLI02246757-65).
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Id. at 150 (emphasis added to cited internal documents). Similarly, JLI disputes the statement "JLI was aware that the JUUL [...] obviously delivered too much nicotine," (JLI Mot. 4 at 21), but the surrounding testimony shows that Dr. Eissenberg uses his expertise to provide meaningful analysis of data. He looks at two tables comparing tobacco products that were tested for nicotine and opines on the differences between the two. He then says:

One potential reason for the difference observed in Tables 1 and 2 is that JLI was aware that the JUUL product they had sold since June, 2015 and that was used in

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the studies identified in Table 1 obviously delivered too much nicotine and was therefore responsible for the dramatic increase in nicotine self-administration among individuals who were previously nicotine naive (especially youth and young adults; e.g., Valone et al., 2020; Leventhal et al., 2019).

Id. at 58 (emphasis added). These statements (and all the others cited by JLI), when viewed within the appropriate context, are clearly not speculative. Because JLI does not challenge the factual support for Dr. Eissenberg's opinions, this Court should deny JLI's motion.

m. Dr. Michael Shihadeh.

JLI offers a make-weight argument against Dr. Shihadeh's so-called "state-of-mind" opinions, which consists of two conclusory sentences. Because JLI does not challenge the factual basis for the opinions or Dr. Shihadeh's expertise, this Court can easily reject JLI's argument. JLI's reference to a discussion of the "purportedly 'deliberate measure' to increase 'TPM'" in Dr. Shihadeh's report is bereft of explanation other than an accusation that it is outside Dr. Shihadeh's field. (JLI Mot. 4 a 21).

JLI Ex. 23, Shihadeh Rpt. at 23-24,

factually supported by the evidence, not speculation as JLI incorrectly contends.

n. Dr. Jonathan Winickoff.

Dr. Winickoff is a highly-qualified expert on nicotine and its effects on children. He is an esteemed pediatrician at Massachusetts General Hospital and Professor of Pediatrics at Harvard Medical School. JLI Ex. 25, Winickoff Rpt. at 2. He served for seven years as Chair of the American Academy of Pediatrics (AAP) Julius Richmond Center of Excellence Tobacco Consortium, leading a national group of researchers to address tobacco control issues that affect children, adolescents, young adults, and family members. *Id.* Currently, he is the Director of Translational Research for the AAP Richmond Center, where he translates tobacco control research into clinical practice, public policy, and real-world community strategies using tobacco control initiatives to improve the public health of nation's youth. *Id.* He is also the current Director of Pediatric Research at the

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Massachusetts General Hospital (MGH) Tobacco Research and Treatment Center. *Id.* He has authored or co-authored over 150 peer-reviewed publications involving tobacco/nicotine (including studies related to e-cigarettes and youth), *id.* at 3-4, and he has been part of the building and updating of a tobacco control maintenance of certification module – *Eliminating Tobacco Use and Exposure. Id.* at 6. Dr. Winickoff has drafted key tobacco control policy for the AMA, AAP, and APA and has testified before Congress about tobacco products, including e-cigarettes and JUUL specifically. *Id.* at 6-7.

As it has for other experts, JLI challenges any mention by Dr. Winickoff of JLI's knowledge or awareness of any fact. Likewise, JLI ignores both the evidence and expertise that support the expert's opinions. In one challenged statement, Dr. Winickoff offers, "JLI understood very well what tobacco companies were and were not permitted to do, including as it relates to flavored products" JLI Ex. 25, Winickoff Rpt. at 183.

id. at 182 (citing Richardson Exhibit 5004, INREJUUL_00057291),

Id. at 182-183 (citing Richardson Exhibit 5008, JLI00368259). Since Dr. Winickoff is reporting about facts, the fiction in JLI's motion should not be accepted. This

o. Dr. Alicia Casey.

Court should reject JLI's motion

In typical fashion, JLI contests a select few of Dr. Casey's opinions as "intent" opinions without mentioning the factual basis of her opinions. For instance, JLI highlights Dr. Casey's statements on JUUL's knowledge of the chemicals in JUUL products ("JLI was aware of the presence of these chemicals" JLI Ex. 1, Casey Rpt. at 16, and "JUUL knew that the aerosols contained multiple toxins," *id.* at 14) without acknowledging that these statements are part of Dr. Casey's substantive discussion about the data and studies identifying multiple toxic chemicals in the JUUL system. *Id.* at 14-17. Dr. Casey's opinion is supported by multiple studies and data

Chenyue Xing, Vol. II, June 23, 2021, at 349:13-353:2; 359:23-360:12; 361:2-18; and 389:14-392:3; *see also*, JLI00514103, JLI04627286 and JLI0462787; Xing Dep. Vol. II at 370:19-382:21; JLI04693751). Because JLI cannot legitimately challenge these facts supporting Dr. Casey's opinions, this Court should deny the motion.

p. Dr. Kurt Ribisl.

Dr. Ribisl is a professor who chairs the department of health behavior at UNC Gillings School of Global Public Health at UNC Chapel Hill. JLI Ex. 22, Ribisl Rpt. at 2. His primary research is in tobacco regulatory science with a focus on sales and marketing of tobacco products at retail and online vendors. *Id.* He has over twenty-five years of experience in tobacco control policy research and has published over 160 scientific articles focused on tobacco control. *Id.* He was a contributing author to multiple US Surgeon's General reports on tobacco use including: Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General (2012), and E-cigarette Use Among Youth and Young Adults: A Report of the Surgeon General (2016). *Id.* He led studies examining the sale of cigarettes and e-cigarettes to minors over the internet, *id.* at 2-3, which were instrumental to the passage of federal laws and regulations prohibiting these types of sales. *Id.* Even this condensed resume demonstrates that Dr. Ribisl is an expert in tobacco regulatory science, particularly as it relates to youth. This background qualifies him to opine on documents related to JUUL's marketing and sales to youth. Contrary to JLI, Dr. Ribisl requires no background in corporate governance to render his opinion.

Nor should he since JLI does not even challenge the factual basis for Dr. Ribisl's opinions about what JLI knew. For example, JLI disputes Dr. Ribisl's opinion that "JLI knew that high numbers of youth were using their products." (JLI Mot. 4 at 22). However, the full statement shows that Dr. Ribisl's opinion is well-supported by record evidence:

It is my opinion that JLI knew that high numbers of youth were using their products and that underage youth were gaining access to JUUL products from widespread media reports. scientific studies.

JLI Ex. 22, Ribisl Rpt. at 10 (emphasis added). JLI again ignores the context and supporting evidence for Dr. Ribisl's opinion that "JUUL knew that their age verification procedures were not

1	adequate" (Mot. 4 at 22).
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4	JLI Ex. 22, Ribisl Rpt. at 48. Because JLI does not challenge the reliability of
5	Dr. Ribisl's opinions, this Court should deny its motion.
6	q. <u>Dr. Robert Proctor.</u>
7	Dr. Robert Proctor is also qualified to opine on what JLI knew or should have known based
8	upon the record. Dr. Proctor, a professor at Stanford University, is an expert in the history of
9	nicotine and the tobacco industry. JLI Ex. 20, Proctor Rpt. at 2. He has conducted extensive research
10	and published many books on the history, marketing, health effects, and manufacturing of tobacco
11	products. Id. He has closely examined "the history of the growth of knowledge of tobacco-cancer
12	links." Id. Dr. Proctor has received multiple awards and honors for his scholarly work, and he is a
13	prominent expert in tobacco litigation. <i>Id</i> .
14	Moreover, JLI does not challenge the factual basis for Dr. Proctor's opinions. For instance,
15	JLI disputes Dr. Proctor's statement that "JLI made an effort to appear more like a responsible
16	corporate citizen," (JLI Mot. 4 at 23), even though internal company documents support the
17	statement and showed JUUL's actions to dampen its youth appeal, including
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19	JLI Ex. 20, Proctor Rpt. at 45 (citing to
20	INREJUUL_00178377; JLI00219757; INREJUUL_00061469; INREJUUL_00061470). JLI also
21	highlights a statement from Dr. Proctor's Executive Summary section that sums up a point
22	demonstrated throughout his report, that JLI "clearly knew that its marketing would reach and
23	appeal to youth." Id. at 4. JLI fails to acknowledge the plethora of record evidence supporting this
24	opinion,
25	id. at 27 n.69 (citing Cohen Dep. at 424-425),
26	<i>id.</i> at 44-45
27	<i>id.</i> at 45, just
28	to cite a few. Because JLI does not question the record evidence that supports Dr. Proctor's

opinions, this Court should deny its motion. *See Jacobson v. R.J. Reynolds Tobacco Co.*, 2013 WL 12094860, at *2 (S.D. Fla. Sept. 20, 2013) ("Dr. Proctor may testify about these documents in terms of historical fact, and what they reflect in connection with relevant issues in this case (as, for example, Defendants' evolving knowledge of and corporate policies with respect to the addictive properties of nicotine and the health risks that came to be associated with smoking).").

<u>Plaintiffs' Experts Permissibly Opine on Legal Standards Using Legal Terms</u> to Assist the Trier of Fact in This Complex Case, not to Usurp the Jury's

Role.

C.

JLI argues that Plaintiffs' experts offer "impermissible legal opinions." JLI's argument is both procedurally and substantively flawed. Initially, a *Daubert* motion is not the appropriate vehicle to make such evidentiary arguments about the parameters of anticipated expert testimony. Such arguments are better suited for trial. *See Plexxikon Inc. v. Novartis Pharms.*, 2020 WL 2301213, at *2 (N.D. Cal. May 8, 2020). More importantly, as explained below, JLI's argument overshoots its mark. The fact that an expert references a legal term or doctrine does not *ipso facto* make their testimony improper.

1. JLI's Arguments are Premature.

This Court has held that arguments about the precise language an expert should use under the Federal Rules of Evidence are better suited for trial. *Abdo v. Fitzsimmons*, 2020 WL 4051299, at *5 (N.D. Cal. July 20, 2020) (citing *N. County Communs. v. Verizon Global Networks*, 2010 WL 11453258, at *1 (S.D. Cal. Nov. 10, 2010)); *see also DeFazio v. Hollister*, 2009 WL 276758, at *1 (E.D. Cal. Feb. 5, 2009) (motions to exclude expert opinions as impermissible legal opinions were "of a type better suited for determination at trial"); *In re Real Estate Assocs. Ltd. P'ship Litig.*, 2002 WL 31027451, at *1–2 (C.D. Cal. Aug.29, 2002) (motion to exclude an expert testimony premature); *In re Actos (Pioglitazone) Prods. Liab. Litig.*, 2014 WL 120973, at *12-13 (W.D. La. Jan. 10, 2104) (concerns that party may offer an impermissible legal opinion is proper subject of a motion *in limine* or objection at trial—not a *Daubert* motion to exclude). This is exactly the type of issue that is properly determined during trial when the issue is squarely before the Court. JLI's motion should be denied as premature.

2. Experts can Testify About Ultimate Issues Under Rule 704(a).

Contrary to JLI's argument, the Ninth Circuit has held under Rule 704(a) that experts can testify about the ultimate issue in a case. *See Hangarter*, 373 F.3d at 1017 ("[A] witness may properly be called upon to aid the jury in understanding the facts in evidence even though reference to those facts is couched in legal terms."). Indeed, experts may reference a legal term or standard in providing their opinions, including when it embraces an ultimate issue. Fed. R. Evid. 704(a) ("An opinion is not objectionable just because it embraces an ultimate issue."); *Davis*, 927 F.2d at 1484-85 ("Fed. R. Evid. 704 allows expert witnesses to express an opinion on an ultimate issue to be decided by the jury."); *Microsoft v. Motorola*, 2013 WL 4008822, at *12 (W.D. Wash. Aug. 5, 2013). This is particularly true "in a more complicated case or a case dealing with a concept less familiar to ordinary jurors" because "expert testimony on an ultimate issue may be useful for guiding the trier of fact through a complicated morass of obscure terms and concepts." *Id.* at *12.

This is true even if the ultimate issue requires the expert to refer to the law in expressing a factual opinion. See, e.g., Hangarter, 373 F.3d at 1017 (permitting expert under Rule 704(a) to testify about how defendants deviated from industry standards which supported a finding of "bad faith"); Davis, 927 F.2d at 1484-85 (expert can testify under Rule 704(a) that defendant acted recklessly); Huson, 9 F.3d 1551 (expert can testify under Rule 704(a) that defendant acted intentionally and recklessly). See also In Re Toyota Motor Corp. Unintended Acceleration Mktg., Sales Practices, and Products Liab. Litig., 978 F. Supp. 2d 1053, 1087-87 (C.D. Cal. 2013) (allowing expert to testify that product is "defective"). [68] Ignoring the controlling holdings in Hangarter and Davis, JLI claims that experts can never use words like "negligence," "reckless," "defective," "duty," "foreseeable," "reasonable," "irresponsible," "misleading," or even "false." This Court should reject JLI's argument that certain magic words are off-limits, which is

⁶⁸ Defendant cites *In re ConAgra Foods*, 302 F.R.D. 537, 558 (C.D. Cal. 2014), to argue that the words "false" and "deceptive" are categorically off-limits for experts. Respectfully, the *ConAgra* decision does not address the binding decisions in *Hangarter* and *Davis*, which held that experts can testify under Rule 704(a) that defendants acted in "bad faith" and "recklessly." Because the Ninth Circuit held in *Hangarter* and *Davis* that experts may use words and phrases that overlap with the applicable legal standard, *ConAgra* is not persuasive.

inconsistent with binding precedent.

The cases that JLI cites are distinguishable legally and factually. For example, JLI cites a number of cases that did not consider Rule 704(a). *See Gallardo v. AIG Domestic Claims*, 629 F. App'x 783, 785 (9th Cir. 2015); *United States v. Scholl*, 166 F.3d 964 (9th Cir. 1999); *Gable v. Nat'l Broadcasting*, 727 F. Supp. 2d 815, 835 (C.D. Cal. 2010). When the Ninth Circuit has addressed Rule 704(a), as it did in *Hangarter*, *Davis*, and *Huson*, it recognized that experts can testify about ultimate issues in a case—even if the expert's opinion is couched in legal-sounding terminology.

In the cases cited by JLI, the excluded experts offered reports read more like jury instructions than expert opinions, and the Courts excluded the opinions as they did not want the expert to supplant the Court's role in instructing the jury on the applicable law to apply. These cases are easily distinguished on their facts. For example, unlike in *Gallardo*, Plaintiffs' experts do not provide "bare legal conclusion[s,]" and each opinion fits the facts of this case. *Gallardo*, 629 F. App'x at 785.⁶⁹ This case is also unlike *Scholl* where the expert would have testified that the criminal defendant had a reasonable view on the legality of their conduct. *See Scholl*, 166 F.3d at 973. This case is also nothing like *Gable*, 727 F. Supp. 2d at 835, where the expert's report "read much like a third legal brief," conducted a "comprehensive review of Ninth Circuit jurisprudence," and "conclude[d] that a triable issue of fact exists."

Duncan also supports Plaintiffs' position. United States v. Duncan, 42 F.3d 97, 101-02 (2d Cir. 1994). In Duncan, the Second Circuit affirmed the admission of expert testimony even though the expert used language that closely tracked the object of one of the charged conspiracies. Id. The Duncan court concluded that "posited factual conclusions [] are not prohibited even if they embrace an ultimate issue to be decided by the jury." Id. at 103.

In *Nationwide*, while the Court determined that the district court did not abuse its discretion by excluding Nationwide's expert's opinions on whether defendant was obligated to follow a provision of the UCC, it acknowledged that a district court may also admit such evidence.

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⁶⁹ The Court in *Gallardo* did not elaborate on the content of the expert's opinion at issue, so the decision is also unhelpful for that reason.

Nationwide Transport Fin. v. Cass Info. Sys., 523 F.3d 1051, 1059 (9th Cir. 2008) ("Although Nationwide is correct in noting that a district court does not abuse its discretion in allowing experts to use legal terminology, this does not prove Nationwide's argument, i.e., that a district court per se abuses its discretion when it *excludes* testimony instructing the jury on legal issues."). The *Nationwide* court was also persuaded by the fact that the expert's legal conclusions "constituted erroneous statements of law," which has not been alleged here.

Unlike JLI's authorities, the Plaintiffs' experts give opinions that are much more like the permissible opinions in *Hangarter*, *Davis*, and *Huson*. As in these cases, this Court should reject JLI's argument under Rule 704(a). For most of Plaintiffs' experts, JLI simply argues that an expert used a magic word, which is—in JLI's view—forbidden. Those arguments are fully addressed by Plaintiffs' legal argument above. For a few experts, JLI also makes contextual arguments. Those are addressed below.

3. This Court Should not Exclude Industry Standard Opinions.

JLI asks the Court to exclude Dr. Drumwright's discussion of marketing-related norms and standards of care, his interpretation of the TCA and FDCA, and his discussion of FTC regulations. JLI Ex. 5, Drumwright Rpt. at 47-49, 50-52, 89-90. JLI also argues that Dr. Emery impermissibly opined that it was required to follow the TCA. JLI Ex. 7, Emery Rpt. at 7, 33. JLI's arguments are inconsistent with Rule 704(a) and Ninth Circuit precedent previously noted. In addition, an expert may testify regarding industry standards even if it supports a finding that JLI acted unlawfully. *King v. GEICO Indem. Co.*, 712 F. App'x 649 (9th Cir. 2017). Tellingly, even the cases cited by JLI support Plaintiffs' position. *See, e.g., In re Baycol Prods. Litig.*, 532 F. Supp. 2d 1029, 1054 (D. Minn. 2007) (expert may testify as to the standard of care); *In re Methyl Butyl Ether (MTBE) Prods. Liab. Litig.*, 643 F. Supp. 2d 482, 504-05 (S.D.N.Y. 2009) (expert may testify as to whether defendant acted outside of established guidelines).

Moreover, courts in the Ninth Circuit have specifically held that experts may opine on whether the facts support whether a party has violated a statute or regulation. *See, e.g., Salas v. Life Care Centers of Am.*, 2008 WL 11340028, at *1 (C.D. Cal. Jan. 15, 2008); *Jarecke v. Am. Nat. Property & Cas.*, 2014 WL 5859535, at *5 (D. Mont. Nov. 12, 2014); *Oyarzo v. Toulumne Fire*

Dist., 2013 WL 5718882, at *16 (E.D. Cal. Oct. 18, 2013) (citing Fed. R. Evid. 704(a)) (denying motion to exclude expert opinions regarding California's OSHA statute)); *United States v. Holmes*, 2021 WL 2035177, at *4 (N.D. Cal. May 21, 2021) ("The Ninth Circuit has permitted experts to testify about industry standards even where the testimony relie[s] in part on [the expert's] understanding of the requirements of [...] law.").⁷⁰

4. <u>Dr. Bonnie Halpern-Felsher Does not Give Legal Opinions About the Master Settlement Agreement, Tobacco Control Act, or FDA Deeming Act.</u>

JLI argues that Dr. Halpern-Felsher impermissibly discusses the requirements of the Master Settlement Agreement, the Tobacco Control Act ("TCA") and the FDA Deeming Act. (JLI Mot. 4 at 30). However, Dr. Halpern-Felsher is not offering her own legal conclusion; rather she is citing to an article discussing the promotion of tobacco products on Facebook in light of the fact that there were no federally imposed restrictions governing their advertisement when e-cigarettes were first introduced. JLI Ex. 10, Halpern-Felsher Rpt. at 65. JLI also argues with no legal support that Dr. Halpern-Felsher's statements about the Master Settlement Agreement should be excluded because they were "juxtaposed" with a discussion of JLI's conduct. This Court should deny JLI's motion because Dr. Halpern-Felsher expressly indicates that she is not opining on "whether [JLI] should have complied with the Master Settlement Agreement." JLI Ex. 39, Halpern-Felsher Dep. at 146:4-17.

5. <u>Dr. Jonathan P. Winickoff Relies on Record Evidence to Reach his "Duty" Opinion.</u>

In the passages identified where Dr. Winickoff opines on JLI's "duty," Dr. Winickoff is summarizing the conclusions attributed to other sources. For example, Dr. Winickoff relies on the Cohen and Kania depositions, JLI Ex. 25, Winickoff Rpt. 190, and he also relies on JLI's recent PMTA application to the FDA where JLI acknowledged that JUUL would appeal to youth; *id.* at 191, 205. Dr. Winickoff also cites JLI's 2017 studies (post-JUUL launch) which showed that adult smokers were satisfied with much lower nicotine concentrations. *Id.* at 194. The fact that

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⁷⁰ JLI's reliance on *Zeigler v. WellPet LLC*, 526 F. Supp. 3d 652 (N.D. Cal. 2021) is misplaced as *Zeigler* involves the exclusion of lay testimony where expertise is required. .

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27 28 Dr. Winickoff uses the term "duty" does not make those portions of his report improper excursions into this Court's province; rather, his use of word assists the trier of fact in determining what was required of JLI together with its corporate knowledge at various points in time.

Eric N. Lindblom is Qualified and his Methodology is Sound.

Mr. Lindblom is an independent consultant on legal and policy matters primarily related to tobacco product regulation with over twenty years' experience working on tobacco control policy, JLI Ex. 15, Lindblom Rpt. at 1, including as Director of the Office of Policy at FDA's Center for Tobacco Products. Id. During his tenure, he was "directly involved in every major decision" and FDA action taken relating to tobacco products. Id. at 3. In the testimony JLI challenges here, Lindblom opines on the regulatory standards applicable to the development and marketing of JUUL given the legal backdrop governing tobacco products. *Id.* at 7.

JLI argues, against this Court's prior rulings, that the Tobacco Control Act ("TCA") promulgates the only applicable standard related to the design and marketing of JUUL products. See In re JUUL Labs, Inc., Mktg., Sales Pracs., & Prod. Liab. Litig., 497 F. Supp. 3d 552, 591 (N.D. Cal. 2020) (rejecting this argument). Plaintiffs will not relitigate here a preemption issue presented as a *Daubert* challenge of their regulatory expert. *See supra*, at Section IV.

As to JLI's challenges to Mr. Lindblom's methodology, Plaintiffs demur on two grounds: first, his opinions are not purely subjective, and second, Mr. Lindblom's opinions are relevant and fully supported. (JLI Mot. 4 at 26-29). In preparing his report, Lindblom reviewed his own publications and the record evidence, relying on his decades-long experience reviewing scientific literature, government and academic survey data, internal industry documents, FDA materials, and court rulings related to tobacco regulation. JLI Ex. 15, Lindblom Rpt. at 6. JLI provides no analysis of any alleged deficiencies in the list of materials Lindblom considered in preparing his expert report, id. at Exhibit C, and instead repeatedly mischaracterizes Lindblom's deposition testimony.

First, JLI argues that Lindblom "confirmed at his deposition that his methodology consists of little more than a 'legal and policy analysis' in which he 'look[s] at what the statute and legislative history says' and then applies 'basic common law and common sense principles of responsible (and inappropriate) business behavior[.]" (JLI Mot. 4 at 27). JLI excerpts Lindblom's

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testimony specifically about his process in reviewing the TCA's "appropriate for the protection of the public health" standard, which he explained involved reviewing the statute itself, its legislative history, related FDA public statements, and the academic literature. JLI Ex. 44, Lindblom Dep. at 12-20. Essentially, in reaching the opinions in his report, Lindblom conducted a review relevant to the specific question he was addressing. *Id.* at 221:11-25. JLI offers no explanation why a trained lawyer with Lindblom's background and FDA experience directly related to tobacco regulation would not be qualified to reach a conclusion based on such a review or how such a review is methodologically flawed. *See In re Bard IVC Filters Prods. Liability Litig.*, 2017 WL 6523833, at *1 (D. Ariz. Dec. 21, 2017) (experts with experience as an FDA medical officer and former FDA Commissioner were qualified to opine on the FDA regulatory process based on their knowledge, experience, and training); *Xarelto*, 2017 WL 1352860, at *2 (denying motion to exclude testimony of former FDA Commissioner, both a physician and lawyer, regarding regulatory process applicable to defendant's pharmaceutical drug).

Second, JLI seeks to exclude Lindblom's opinions because he was supposedly unable to identify a publication directly repeating his opinion on FDA implementation of the Tobacco Control Act. (JLI Mot. 4 at 27). Notwithstanding JLI's effort to portray Mr. Lindblom's testimony in a bad light, that effort is only accomplished by mischaracterizing Lindblom's deposition testimony, which reads in full:

Q. Have you seen anywhere in the published literature anybody who agrees with your views on how the FDA has done under the TCA?

A. I have not ever encountered – making these kinds of statements in numerous articles, presentations, at conferences, and so forth, I have never had anybody contradict me or argue to the opposite.

JLI Ex. 44, Lindblom Dep. 218:17-25. To be clear, Mr. Lindblom states that he has "never looked for that because nobody has ever said they don't agree with it so it just hasn't been an issue [...] to look for it." *Id.* at 219:6-9. Regardless, depending on which specific opinion JLI is looking for published agreement, Mr. Lindblom's report contains examples where various parties have shared his concern about the need for greater FDA action on ENDS products and published accordingly. *See, e.g.* JLI Ex. 15, Lindblom Rpt. at 16, n. 23 (discussing a letter from public health and medical

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groups to FDA Commissioner Gottlieb on the need for immediate action to protect young people from Juul e-cigarettes). That said, JLI points to no authority that a regulatory expert would need such support to render his opinions admissible. Nor could it, since *Daubert* and its progeny make clear that as long as the expert's opinion is methodologically sound and reliable, even a unique opinion is admissible. *Daubert*, 509 U.S. at 595.

Finally, JLI objects to Lindblom's discussion of the obstacles to FDA regulation of tobacco products, JLI Ex. 15, Lindblom Rpt. at 18-25, which JLI opposes as irrelevant and speculative. (JLI Mot. 4 at 27-28). JLI has already indicated that it intends to use FDA inaction as a defense and that tobacco regulations constitute the only source relevant to the legal standards applicable to JLI's development and marketing of JUUL products. Indeed, as mentioned, JLI submits here that the TCA's "appropriate for the protection of public health" is the only applicable standard for JLI products. *Id.* at 27. While Mr. Lindblom has noted the wide discretionary latitude given to FDA in implementing the TCA, JLI Ex. 44, Lindblom Dep. at 185:9-18, identifying factors leading to FDA inaction are necessary to prevent a defensive conflation of that inaction with FDA endorsement of the status quo. *See Providence Journal Co. v. United States Dep't of the Army*, 981 F.2d 552, 558 (1st Cir. 1992) (finding that FDA's lack of action does not constitute an adoption of the earlier decision; agency adoption cannot be inferred from agency inaction).

This Court should allow Mr. Lindblom to draw on his experiences occupying senior positions in the Office of Policy at FDA's Center for Tobacco Products to provide insight on the—as he describes—"extraordinarily difficult internal, behind-the-scenes clearance process that FDA has to go through" to effectuate policy. JLI Ex. 15, Lindblom Rpt. at 12-14. Lindblom's work with the agency informs his discussion throughout of the bureaucratic hurdles and multifaceted considerations influencing FDA action (and inaction) and uniquely qualifies him to render his opinions. *Id.* at 20, n. 39.

7. Conclusion

For all the foregoing reasons, JLI's Motion #4 should be denied.

IX. JLI MOTION #5: FAILURE TO ACT

JLI seeks to exclude opinions regarding: i) its lack of warnings about nicotine addiction and health effects; ii) its failure to conduct pre-launch randomized, controlled clinical studies and toxicological testing; and (iii) its failure to maintain quality control and manufacturing processes to product features that result in variable nicotine spikes. (See generally JLI Mot. 5). JLI claims that these opinions are either preempted or unreliable. JLI's arguments are meritless.

JLI Should Not Be Permitted to Expand this Court's Preemption Ruling to Α. Evidentiary Matters Involving Warnings Claims that are not Preempted

In ruling on preemption, this Court stated that "the vast majority of plaintiffs' state claims may proceed now." See Section IV, supra (generally discussing JLI's preemption arguments and the Court's prior preemption rulings). Unsatisfied, JLI seeks to relitigate preemption in its attempt to convince this Court to exclude opinions concerning the lack of nicotine addiction warnings beyond JUUL's labeling as well as the lack of warnings about JUUL's other health effects. 72 Not only is JLI's motion a thinly veiled attempt to seek reconsideration of the Court's ruling on preemption, but it is a misguided effort to broaden it by placing evidentiary restrictions beyond those that could even arguably flow from that ruling.⁷³ The opinions provided by Plaintiffs' experts are not subject to any preemption ruling, and JLI's efforts to link the two should be denied.

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⁷¹ Order on Substantive Mot. to Dismiss (ECF 1084) at 19.

⁷² JLI Mot. 5 at 2-4 (quoting opinions of Plaintiffs' experts that relate to JLI's general lack of warnings (e.g. "JUUL should have developed a set of warnings on topics such as highly addictive nicotine," [JLI Ex. 16, Noar Rpt.] \P 9.2.1."); JLI Mot. 5 at 5 ("Although the court has not yet held that health labeling issues are preempted, these additional facts and the same reasoning—that the FDA has considered and made a determination on this issue—render Plaintiffs' experts' healthrelated opinions preempted and irrelevant.").

To the extent that JLI says that Plaintiffs have waived their claims related to JLI's failure to warn of nicotine addiction on product labeling, JLI is mistaken. Plaintiffs have not waived their ability to seek review and proffer evidence in support of these claims.

⁷³ This Court's other preemption rulings likewise impose no preclusive effect on Plaintiffs' expert testimony. In *Colgate I*, this Court determined that the TCA exception clause "expressly excepts advertisements from preemption and no aspect of plaintiffs' claims based on allegedly misleading or fraudulent advertising is preempted by the TCA, including the issue of warning consumers about the potency and addictiveness of JUUL's benzoic acid and nicotine salt formulation." Colgate v. JUUL Labs, Inc., 345 F. Supp. 3d 1178, 1190 (N.D. Cal. 2018). The Court concluded "[p]laintiffs' causes of action based on advertisements or the mislabeling of the amount of nicotine contained in each pod are not preempted by the TCA." *Id.* The Court revisited this issue in *Colgate II*, where it

B. <u>JLI's Remaining Challenges to Plaintiffs' Experts' Warnings Opinions are Meritless.</u>

1. <u>Plaintiffs' Experts Permissibly Opine as to Adequacy of JUUL's</u> Warnings

JLI next takes aim at the warnings opinions of Plaintiffs' experts, claiming they amount to "impermissible legal conclusions" as to JLI's failure to warn. (JLI Mot. 5 at 4, 5). ⁷⁴ But "[t]he adequacy of a warning is generally a question of fact." *Altman v. HO Sports Co., Inc.*, 821 F. Supp. 2d 1178, 1188 (E.D. Cal. 2011) (citations omitted). Courts, in turn, have routinely allowed expert testimony to assist the jury in evaluating this key issue. *See, e.g., Deutsch v. Novartis Pharms. Corp.*, 768 F. Supp. 2d 420, 440-41 (E.D.N.Y. 2011); *see also Rodriguez v. JLG Indus., Inc.*, No. CV1104586MMMSHX, 2012 WL 12883784, at *10-12 (C.D. Cal. Aug. 3, 2012) (permitting testimony by human factors expert on the adequacy of warnings). This is "a commonly accepted methodology used by experts admitted to testify as to the accuracy of warnings." *Deutsch*, 768 F. Supp. 2d at 440-41 (citing *In re Diet Drugs Prods. Liab. Litig.*, No. MDL 1203, 2000 WL 876900, at *12 (E.D. Pa. June 20, 2000)); *see also Phelps v. Wyeth, Inc.*, 938 F. Supp. 2d 1055, 1079 (D. Or. 2013) (observing that "[a] warning's adequacy is a proper subject of expert testimony" (quotation omitted)); *Beale v. Biomet, Inc.*, 492 F. Supp. 2d 1360, 1369 (S.D. Fla. 2007) ("[A]s a general rule, expert testimony is required to determine the adequacy of a warning ...").

JLI ignores these authorities and instead relies on distinguishable cases involving unqualified experts or the lack of a duty to warn of obvious dangers. *Strong v. E.I. Dupont de Nemours Co., Inc.*, 667 F.2d 682, 687 (8th Cir. 1981) (holding that a pipe manufacturer had no duty to warn of the possibility of explosions because that danger was "well known throughout the

reiterated its previous ruling that allegations that "are either about advertisements or about the strength of JUUL's nicotine liquid" are not preempted. *Colgate v. JUUL Labs, Inc.*, 402 F. Supp. 3d 728, 745 (N.D. Cal. 2019). As with its October 23, 2020 ruling in this case, in *Colgate I*, the Court construed its preemption ruling as "narrow" concluding that most of plaintiffs' state law claims were not preempted, except for a narrow set of claims based on allegations that "the product label fail[s] to disclose the greater potency and addictiveness of JUUL's benzoic acid and nicotine salt formation." *Colgate I*, 345 F. Supp. 3d at 1189.

⁷⁴ In Section VIII.C.2, *supra*, Plaintiffs respond to JLI's general claim that Plaintiffs' experts offer legal conclusions, (JLI Mot. 4 at 24-34). Plaintiffs respectfully incorporate those arguments here.

industry"); Calvit v. Procter & Gamble Mfg. Co., 207 F. Supp. 2d 527, 529 (M.D. La. 2002) (finding expert lacked qualifications to offer warnings opinion); Alnahhas v. Robert Bosch Tool Corp., Case No. CIV-13-178-D, 2018 WL 2293965, at *4 (W.D. Okla. May 18, 2018) (same); In re C.R. Bard, Inc., 948 F. Supp. 2d 589, 629 (S.D. W. Va. 2013) (permitting expert testimony but precluding use of certain legal terminology). Accordingly, allowing Plaintiffs' experts to testify as to the adequacy of JLI's warnings is well within the ample discretion afforded to district courts under Daubert.

2. <u>Plaintiffs' Experts Reliably Opine on the Lack of Health Effects</u> Warnings

JLI asserts that this Court should exclude Plaintiffs' experts because they provided "no analysis showing that there was a risk about which to warn" and that Plaintiffs' experts are otherwise unqualified to offer their health warnings opinions. (JLI Mot. 5 at 6-9). Both arguments are flawed.

a. <u>JLI's Arguments on Dosage are Unpersuasive.</u>

JLI claims that Plaintiffs' experts' opinions on health effects are unreliable because Plaintiffs' experts have not done an analysis to determine whether users are exposed at a sufficient dosage to toxins that could cause health effects. (JLI Mot. 5 at 6). This argument is flawed for three reasons. First, JLI fails to cite any authority stating that causation must be definitively established before a manufacturer must warn of potential harms. And with good reason—no such authority exists. Indeed, JLI presently warns the public that "nicotine may cause other conditions, such as ... dizziness, nausea, and stomach pain" and that "inhalation of JUUL may aggravate pre-existing respiratory or heart conditions" despite claiming in this litigation that these injuries lack general causation. Pltf. Ex. 29, JLI Package Insert, JLI20003583. Likewise, neither the warnings required by Prop 65 or FDA require reference to dosage.

⁷⁵ JLI reliance to *Yates v. Ford Motor Co.*, No. 5:12-CV-752-FL, 2015 WL 3448905 (E.D.N.C. May 29, 2015) is also misplaced. There, the district court, in an unpublished opinion, prevented an expert from testifying "as to whether a warning was 'adequate' or 'inadequate' …" *Id.* at *8. But as explained in Section VIII.C.2, *supra*, "[a]n opinion is not objectionable just because it embraces an ultimate issue." FED. R. EVID. 704(a); *see also Hangarter v. Provident Life & Acc. Ins. Co.*, 373 F.3d 998, 1016 (9th Cir. 2004).

Finally, it is undisputed that several hazardous chemicals in the JUUL vapor are known to cause respiratory injuries, including some that are carcinogenic. Put another way, JUUL vapor contains certain toxic chemicals for which there is no safe dosage. As one example, Dr. Tackett noted in his report that the levels of methylglyoxal exceed known toxic thresholds. JLI Ex. 24, Tackett Rpt. at 4. Moreover, Plaintiffs' experts have reliably set forth their opinions as to the potential health effects of using JUUL. *See* Section VII(B), *supra*. JLI's assertions about dosage simply ignore the nature of the product it extensively marketed and sold to consumers.

b. Plaintiffs' Experts are Qualified to Render Warnings Opinions

JLI asserts that "Plaintiffs' experts' opinions regarding health warnings are also impermissible for the simple reason that they are outside of the experts' qualifications." But the adequacy of JUUL's warnings is subject to many measures of quality guided by an expert's knowledge and expertise within their respective disciplines. *See*, *e.g.*, *Guido v. L'Oreal*, *USA*, *Inc.*, No. 2:11-CV-01067-CAS, 2014 WL 6603730, at *10 (C.D. Cal. July 24, 2014) ("In the absence of some suggestion that flammability warnings are a distinct field of inquiry, Dr. Misra's general qualifications in the field of attributing value to product features are more than sufficient."); *Triant v. Am. Med. Sys. Inc.*, No. CV-12-00450-PHX-DGC, 2020 WL 4333645, at *3 (D. Ariz. July 28, 2020) (permitting clinician to opine as to adequacy of warnings based on experience seeing patients).

JLI relies on remarks made by Drs. Eissenberg, Tackett, and Casey disclaiming expertise in either warnings or marketing. But courts look beyond isolated statements such as these and evaluate the expert's qualifications alongside the proffered opinion. For instance, in *Pineda v. Ford Motor Co.*, 520 F.3d 237 (3d Cir. 2008), the Third Circuit looked beyond the testimony of a glass engineer who disclaimed expertise in warnings, finding the expert was amply qualified to opine that a vehicle's instruction manual should have contained an explicit warning. *Id.* at 244-245. The Third Circuit noted an important distinction between an expert who "opine[s] on how the warning should be worded or how it should appear in order to effectively convey its message" and an expert who opines that a warning is necessary to safeguard against risks posed by a product. *Id.* Further, challenges to the opinions of a generally qualified expert on the grounds that an expert's

qualifications are not sufficiently specific are not proper under *Daubert. Lewert v. Boiron, Inc.*, 212 F. Supp. 3d 917, 928 (C.D. Cal. 2016). Rather, "[a] lack of specialization affects the weight of the expert's testimony, not its admissibility." *Id.*; *Guido*, 2014 WL 6603730, at *10.; *see also McCullock v. H.B. Fuller Co.*, 61 F.3d 1038, 1044 (2d Cir. 1995).

Here, Drs. Eissenberg, Tackett, and Levy offer no opinions as to how JUUL should have worded a warning nor how it should have been conveyed to consumers. Rather, these experts opine that JLI should have warned about JUUL's health risks and failed to do so. JLI Ex. 6, Eissenberg Rpt. at 33, 112; JLI Ex. 24, Tackett Rpt. at 54-55; JLI Ex. 1, Casey Rpt. at 10. Just as a medical doctor can testify as to the completeness and accuracy of a device label, *In re 3M Combat Arms Earplug Prod. Liab. Litig.*, No. 3:19MD2885, 2021 WL 765019, at *38 (N.D. Fla. Feb. 28, 2021), so too can Plaintiffs' experts on tobacco devices (Dr. Eissenberg) and medical injury (Drs. Tackett and Levy) opine as to the necessity of providing warnings based on the risks posed by products. Plaintiffs' experts, with their years of training and experience, are qualified to evaluate whether a warning was adequate and necessary.

For example, Dr. Eissenberg is a Professor of Psychology and Co-Director for the Center for the Study of Tobacco Products. He has spent two decades researching and publishing on the physiological, subjective, and behavioral effects of new and novel tobacco products. JLI Ex. 6, Eissenberg Rpt. at 5. He has analyzed data to determine the effects of novel tobacco products in humans, including their nicotine delivery profile, subjective effect profile, influence on user behavior, and ability to substitute for traditional tobacco products. *Id.* at 6. He is clearly qualified to testify to the necessity for a nicotine or addiction warning related to a tobacco product.

Likewise, Dr. Tackett is more than qualified to opine on the necessity of a warning regarding JUUL's health effects. Dr. Tackett is a tenured professor of Pharmacology and Toxicology at the University of Georgia. JLI Ex. 24, Tackett Rpt. at 1. He has been involved with FDA regulations as an academician and pharmacologist for over three decades. *Id.* at 3. As part of his teaching responsibilities, he is familiar with the relevant federal regulations as they pertain to chemicals and drug development, clinical trials, pharmacoepidemiology, adverse event reporting

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and analysis, and labeling issues for prescription and OTC medications. *Id.* Dr. Tackett's warnings opinions are squarely within his professional capacity as a toxicologist and pharmacologist.

Next, Dr. Casey's qualifications and experience provide her with a reliable foundation to opine on risks associated with JUUL use and whether JLI needed to warn of those risks. She is a pediatric pulmonologist at Boston Children's Hospital. JLI Ex. 1, Casey Rpt. at 4. She has expertise in caring for children with rare interstitial and diffuse lung disease and in evaluating the pulmonary effects of vaping. *Id.* at 4-5. Dr. Casey established the BCH Pulmonary Vaping Program. *Id.* She has given local, regional, and national lectures on the pulmonary complications of vaping. *Id.* at 5. Of note, she has taught multiple courses at Harvard Medical School and has supervised pediatric residents and pulmonary fellows. *Id.* at 5.

Finally, JLI criticizes Dr. Noar's qualifications to offer his opinions on JUUL's advertising, social media, and product design and their impact on youth use of JUUL. Here can be little question that Dr. Noar is qualified to opine as to JUUL's communication strategies, whether by marketing or product design, as Dr. Noar's specialty is in communication strategy and messaging. JLI Ex. 16, Noar Rpt. at 2. As a professor at the University of North Carolina, Dr. Noar teaches graduate level coursework on messaging and communication campaigns to improve behaviors that prevent disease. *Id.* He has spent significant time in his career on communicating tobacco health risks, including publishing extensively and serving as a Principal Investigator on grants related to youth tobacco prevention messaging. *Id.* at 3-5. Dr. Noar is also sufficiently qualified to opine as to the regulatory framework surrounding tobacco warnings despite not being a lawyer based on his experience with tobacco labeling. Although JLI disagrees with some of Dr. Noar's statements

⁷⁶ JLI also criticizes the reliability of Dr. Noar's opinions related to the impact of JUUL's marketing and product design on youth use. (JLI Mot. 5 at 8-9). These criticisms mimic those raised by JLI in Motion #1 related to Marketing, (JLI Mot. 1 at 22, 37), and Plaintiffs address these arguments *supra*, Section V.C.2.c) and Section V.D.3.c. In summary, Dr. Noar applied a reliable approach in rendering his opinion regarding the impact of JLI's marketing for JUUL and JUUL's product design. He appropriately synthesized the factual record and relevant research, including studies that do not conform to his opinion. JLI Ex. 16, Noar Rpt. at 20-23 (§ 7).

regarding FDA's regulatory authority, this disagreement is not grounds for exclusion—rather, it is fodder for cross-examination.

C. <u>Plaintiffs' Experts Offer Reliable and Relevant Opinions Relating to the</u> Inadequacy of JLI's Prelaunch Testing

JLI has long professed that it entered the tobacco market to help the world's one billion daily smokers switch off combustible cigarettes.⁷⁷ While lofty on paper, this goal existed in the ether with little action taken by JLI to prevent and minimize abuse by youths and the nicotine naïve. *See,.e.g,* Pltf Ex. 30, White Dep. at 289:3-17, Sept. 3, 2021. Indeed, JLI never assessed JUUL's abuse liability and never tested the marketed device in humans before launching. Pltf. Ex. 11, Myers Dep. at 174:4-14; Pltf. Ex. 31, Rouag Dep. at 407:16-408: 2, 408:22-409:1. JLI also failed to test for and identify a host of dangerous chemicals in JUUL aerosol even though it intended for people to inhale it 100-200 times per day. *See, e.g.*, Pltf Ex. 17, Xing Dep. at 389:14-390:9.

See, e.g., Pltf. Ex. 32, Perfetti Dep. at 752:8-15; see also JLI Ex. 18, Prochaska

Rpt. at 57.

⁷⁷ juul.com (stating "[o]ur mission is to transition the world's billion adult smokers away from combustible cigarettes").

Similarly, JLI could have assessed the toxicological profile of the JUUL's vapor prior to launch. JLI Ex. 24, Tackett Rpt. at 20-21. Not only did JLI have the means and opportunity to chemically analyze for toxins, JLI had notice pre-launch that e-cigarette aerosols created by its product contained chemical constituents that posed a significant danger to human health if inhaled. JLI Ex. 24, Tackett Rpt. at 28-30; JLI Ex. 1, Casey Rpt. at 8-10. Yet, JLI chose not to test.

At trial, Plaintiffs intend to offer expert testimony to address these issues, including that JLI could have done the testing described above prior to launch (referred to below as "pre-launch testing") and the likely impact of such testing had it been done. *See*, *e.g.*, JLI Ex. 6, Eissenberg Rpt. at 70, 72-80, 108-111; JLI Ex. 1, Casey Rpt. at 8-10; JLI Ex. 8, Grunberg Rpt. at 39, 51; JLI Ex. 18, Prochaska Rpt. at 55-59; JLI Ex. 23, Shihadeh Rpt. at 51-52; JLI Ex. 24, Tackett Rpt. 20-21; JLI Ex. 25, Winickoff Rpt. at 167-168, 193-194, 231. JLI argues that this testimony does not "fit" the facts of the case because no statute or regulation required JLI to do such testing, and further baselessly claim that Plaintiffs' experts have not done the leg-work to support these opinions here. As explained below, though, these criticisms are either inconsequential or outside the purview of *Daubert* and should be left for trial.

1. The Existence of a Statute or Regulation is Not a Necessary Predicate to the Opinions Offered by Plaintiffs' Experts About JLI's Pre-Launch Testing

JLI claims that Plaintiffs' experts base their pre-launch testing opinions "on the assumption that JLI was required, by federal law or FDA guidance" to conduct randomized clinical trials or toxicological testing (JLI Mot. 5 at 10, 13), and that because no such requirement existed at the time of JUUL's launch, these opinions do not "fit" the facts of the case (*id.*). But whether JLI should have conducted the pre-launch testing is not dependent on the existence of some statute or regulation specifically requiring them to do so (rather, it is dependent upon whether a reasonable tobacco manufacturer would have done so)—nor do Plaintiffs' experts rely solely on federal law or FDA guidance in reaching their opinions.

Instead, Plaintiffs' experts properly rely on their extensive qualifications and experience in rendering their opinions about JUUL's pre-launch testing. *See* Fed. R. Evid. 702 advisory committee notes to 2000 amendment ("Nothing in this amendment is intended to suggest that

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experience alone—or experience in conjunction with other knowledge, skill, training or education—may not provide a sufficient foundation for expert testimony."). For example, JLI attacks Drs. Prochaska, Eissenberg and Shihadeh ⁷⁸ for their opinions that JLI should have conducted randomized clinical trials prior to launch, claiming they "applied the wrong standard." (JLI Mot. 5 at 9-11) But it is JLI that applies the wrong standard. The admissibility of expert opinions is evaluated against the standard set forth in *Daubert*—not the TCA or FDA guidance—and under *Daubert*, admissibility is predicated on a finding that the expert's opinion is reliable and relevant. Under the reliability requirement, the expert testimony must "ha[ve] a reliable basis in the knowledge and experience of the relevant discipline." *Primiano v. Cook*, 598 F.3d 558, 565 (9th Cir. 2010).

Here, Drs. Prochaska, Eissenberg and Shihadeh are uniquely qualified to opine as to the adequacy of JLI's prelaunch testing. They are leaders in the field of tobacco research, have run randomized clinical trials involving tobacco products, and are responsible for a large body of published, peer-reviewed literature that compares JUUL to other products. JLI Ex. 18, Prochaska Rpt. at 1-2, 99-155; JLI Ex. 35, Eissenberg Rpt. at 4-11; JLI Ex. 23, Shihadeh Rpt. at 2-4. JLI's similar criticisms of Drs. Casey's and Tackett's pre-launch toxicological testing opinions fare no better. (JLI Mot. 5 at 12-13). Their opinions are based upon their decades of training, experience, and research in pulmonology, toxicology, and pharmacology, as discussed above, and any references by these experts to federal laws or FDA standards merely illustrate the minimum standards by which a responsible tobacco manufacturer should act.

Importantly, though, JLI does not quibble with the qualifications or methodology employed by Plaintiffs' experts in rendering these opinions. Instead, JLI complains that their pre-launch

See. e.g. JLI Ex. 18.

Prochaska Rpt. at 58

⁷⁸ JLI references Dr. Shihadeh's report in its introductory paragraph (*see* JLI Mot. 5 at 10) but omits any discussion of him in the body of its analysis.

⁷⁹ JLI states that "it would have been unethical" for JLI to conduct randomized, controlled studies on nicotine naïve individuals, and that Plaintiffs' experts should be precluded from opining as to such. Plaintiffs' experts do not offer this opinion.

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testing opinions "do not concern the safety or health effects of JUUL products" and merely reflect the belief that JLI violated some legal requirement. (JLI Mot. 5 at 13). This is simply not so. Plaintiffs' experts do not assume that JLI was legally required to test its product before selling it; in fact, the absence of any such legal obligation made it all the more important for JLI to test to evaluate the safety, including health effects, of its product, which Plaintiffs' experts make clear in their reports. See, e.g., JLI Ex. 6, Eissenberg Rpt. at 74 ("My expert opinion is that failing to investigate systematically the effects of different nicotine liquid... almost certainly contributed to an epidemic of nicotine use/abuse among American non-smokers, including youth"); JLI Ex. 1, Casey Rpt. at 10 ("Repeated inhalation of these toxic chemicals over years will not be low risk to users and is of significant concern."); JLI Ex. 18, Prochaska Rpt. at 55-56 (describing JLI's failure to conduct pre-launch testing to evaluate lower nicotine concentrations and that "[a] lower nicotine strength ... would be a safer alternative than 5% strength, which increases abuse liability, nicotine dependence, and addiction"); JLI Ex. 23, Shihadeh Rpt. at 51 ("[JLI] marketed this potent product [JUUL] without a single clinical study to evaluate ... how using this high concentration product would affect nicotine dependence over months of use."); JLI Ex. 24Tackett Rpt. at 15-19 (describing the deleterious health effects of carbonyls found in JUUL vapor).

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JLI's Other Criticisms of Plaintiffs' Experts are Fodder for Cross 2. **Examination and Otherwise Lack Support**

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Finally, JLI states that Plaintiffs' experts fail to rely on sufficient facts and data in rendering their opinions because they did not establish that pre-launch testing was an industry standard at the time of JUUL's launch (JLI Mot. 12, 13). This too goes to the weight of the expert's opinions and not their admissibility. See M. G. v. Bodum USA, Inc., No. 19-CV-01069-JCS, 2021 WL 718839, at *17 (N.D. Cal. Feb. 24, 2021) (rejecting argument that expert's opinion should be excluded because it is not based on any existing industry or legal standard because "[t]his argument goes to the weight of [the expert's] opinion, not its admissibility under Rule 702 and Daubert"). JLI's quotes to FDA commentary and guidance do not change this calculus. (JLI Mot. 5 at 11). These quotes, which suggest that controlled clinical trials "may" be unnecessary for PMTA authorization in circumstances not present here, are the type of evidence that a jury may consider in evaluating

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what weight to attribute to an expert's testimony. *See Kennedy v. Collagen Corp.*, 161 F.3d 1226, 1230 (9th Cir. 1998) ("[T]he factfinder may be confronted with opposing experts, additional tests, experiments, and publications, all of which may increase or lessen the value of the expert's testimony.").

JLI similarly complains that Drs. Eissenberg and Prochaska's opinions related to pre-launch testing lack sufficient facts and data because they have not "conducted or identified any studies indicating that randomized controlled trials would have enabled JLI to determine the cessation efficacy or a 'minimum' or 'lowest effective dose' for JUUL." (JLI Mot. 5 at 12). First, JLI cites nothing to support this proposition, and the reason is clear:

See, e.g., JLI Ex. 6, Eissenberg Rpt. at 77-80; JLI Ex. 18,

Prochaska Rpt. at 58-59.

Ultimately, JLI's assumption that a legal or regulatory standard is a necessary predicate for admissible expert testimony is incorrect. This assumption is not a reasonable basis to exclude their opinions.

D. <u>Plaintiffs' Experts Offer Reliable and Relevant Opinions About JLI's</u> Inadequate Design of JUUL as it Relates to Nicotine Delivery

There should be no dispute that nicotine's abuse potential is tied directly to the dose and speed of delivery to the blood stream. Pltf. Ex. 11, Myers Dep. at 111:16-112:10. The faster and greater the amount of nicotine delivered to the bloodstream, the greater the risk of addiction. *Id.* JLI knew this and yet JLI's design for JUULpods allowed for variations in the wick-and-coil assembly such that certain pods, depending upon the pod's manufacturer, delivered 40% more TPM (aerosol) than other pods on a per-puff basis. *See*, *e.g.*, Pltf. Ex 30, White Dep. at 154: 20-155:14, Feb. 24, 2021; *see also* JLI Ex. 6, Eissenberg Rpt. at 39; JLI Ex. 13, Levy Rpt. at 27; JLI Ex. 21, Prochaska Rpt. at 54; JLI Ex. 23, Shihadeh Rpt. at 22. The amount of TPM delivered directly correlates with the amount of nicotine delivered because nicotine is in a fixed concentration with the e-liquid. Pltf. Ex. 11, Myers Dep. 268:12-20.

In addition, JLI designed JUUL in such a way that users, in the first four-to-five puffs of a puffing session, received a spike of TPM, and thus a spike of nicotine. Pltf. Ex. 11, Myers Dep. at 115:25-116:6, 268:18-20; see also JLI Ex. 6, Eissenberg Rpt. at 41-49; JLI Ex. 18, Prochaska Rpt. at 4-5, 49-51; JLI Ex. 23, Shihadeh Rpt. at 22-23; JLI Ex. 25, Winickoff Rpt. at 235. Worse yet, JUUL's design allows users to recreate this TPM spike by squeezing or flicking the pod or by podpopping (the user removes and reinserts the JUULpod). Pltf. Ex. 4, Hatton Dep. at 262:6-14; see also JLI Ex. 6, Eissenberg Rpt. at 41-49; JLI Ex. 18, Prochaska Rpt. at 4-5, 49-51; JLI Ex. 23, Shihadeh Rpt. at 22-30; JLI Ex. 25, Winickoff Rpt. at 235.

Plaintiffs' experts opine that the nicotine fluctuations created by the differing JUULpods and TPM spikes increases the abuse liability of JUUL, and that JLI could have designed its products to eliminate these fluctuations and reduce abuse liability. JLI Ex. 6, Eissenberg Rpt. at 38-49; JLI Ex. 18, Prochaska Rpt. at 4-5, 49-54; JLI Ex. 23, Shihadeh Rpt. at 22-30; JLI Ex. 25, Winickoff Rpt. at 235. JLI does not challenge the qualifications of Plaintiffs' experts to offer these opinions. Rather, JLI claims that these opinions are unreliable because no "objective standards" existed requiring it to minimize the increases in nicotine delivery. But the inexistence of a standard did not give JLI free rein to act in any way it chose—and, as explained below, nor does it impact the reliability of the challenged opinions.

1. <u>JLI Attempts to Rewrite the Admissibility Standard for the Plaintiffs' Experts Opinions Concerning the Design of the JUULpods</u>

Prior to launch, JLI subcontracted the manufacture of the JUULpods to Defond, and Defond remained JLI's sole supplier of JUULpods until 2017 when JLI began selling JUULpods manufactured by AFG. Pltf. Ex. 11, Myers Dep. at 231:8-232:10. Testing by JLI in 2017 revealed variability in TPM/nicotine delivery between the two manufacturers' JUULpods, Pltf. Ex. 11, Myers at 384:12-25, with JLI referring to the Defond JUULpod to as the "high TPM" pod and AFG as the "low TPM" pod. Pltf. Ex. 33, Exhibit 2609 from Joshua Vose deposition, JLI00595764; *see also* JLI Ex. 13, Levy Rpt. at 27; JLI Ex. 18, Prochaska Rpt. 53-54; JLI Ex. 23, Shihadeh Rpt. at 19-21.

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at 231:8-232:10. This difference was (and continues to be) permitted by JUUL's specification, and testing revealed that, on average, a TPM variation of 40% between the two suppliers. *Id.*

Plaintiffs' experts opine that the nicotine delivery profiles created by the Defond and AFG JUUL pods increased the abuse liability of JUUL, which JLI should and could have minimized. JLI Ex. 6, Eissenberg Rpt. at 38-40; JLI Ex. 13, Levy Rpt. at 28; JLI Ex. 21, Prochaska Rpt. at 53-54; JLI Ex. 23, Shihadeh Rpt. at 20-21; JLI Ex. 25, Winickoff Rpt. at 115. Just as it claims above with regard to pre-launch testing, JLI again asserts that no "objective" standard existed "that would have applied to the manufacturer of the wick and coil, or which would have been knowable to JLI prior to receiving Plaintiffs' experts' litigation-driven techniques." (JLI Mot. 5 at 15). This is an argument for trial, not *Daubert*. As explained above, an "objective" standard like the type contemplated by JLI is not a requirement for admissibility under *Daubert*. The facts are: (1) the JUUL device submitted for PMTA and in the marketplace today (AFG-type pods) has different characteristics than the device used by consumers through mid-to-late 2017, see JLI Ex. 18, Prochaska Rpt. at 54 (explaining history of JUULpods and sourcing for JUULpods for PMTA); (2) from 2017 through early 2019, a consumer might buy Defond pods that, at the high end, delivered five times the per-puff nicotine deliveries of a "low TPM" AFG pod, Pltf. Ex.11, Myers Dep. at 384:12-25, and (3) all of this could be compounded by the TPM/nicotine spike which itself could be reproduced by "pod popping" or simply having the device bouncing around in one's pocket, Pltf. Ex. 4, Hatton Dep. at 262:6-14; see also Section IX.D.2, infra. Plaintiffs' experts rely on these and other facts and not "litigation-driven techniques" as suggested by JLI.

In addition, Plaintiffs' experts base their opinions related to the flawed JUULpods on their experience and education. For instance, JLI criticizes Dr. Shihadeh's opinion that JLI could have minimized the potential for nicotine variability in its design of the wick-and-coil assembly, arguing that Dr. Shihadeh fails to cite "an objective, applicable standard." (JLI Mot. 5 at 15) But Dr. Shihadeh doesn't need to cite a standard—his education and experience as applied to the facts

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of this case serve as a reliable foundation for his opinions. *See United States v. Bazaarvoice*, Inc., No. 13-CV-00133-WHO, 2014 WL 11297188, at *2 (N.D. Cal. Jan. 21, 2014) ("[E]ven in the age of Daubert and Kumho, experience-based experts may testify on matters within their expertise." (internal citation omitted)). As the Dean of Maroun Samaan Faculty of Engineer and Architecture and a Professor of Mechanical Engineering at the American University of Beirut (AUB), Dr. Shihadeh has devoted his career to the study emerging tobacco products, including the design of e-cigarettes. JLI Ex. 23, Shihadeh Rpt. at 2. Dr. Shihadeh founded the AUB Aerosol Research Laboratory, which is world leading science and technology hub for the study of emerging tobacco products and receives significant funding, including current funding by US NIH/FDA, to research e-cigarette aerosols. *Id.* at 3. He has published extensively on e-cigarettes, including how e-cigarette design choices can impact aerosols. *Id.* at 3-4. His qualifications provide more than sufficient support for his opinions. JLI's insistence on an "objective standard" is contrary to the law and is belied by Dr. Shihadeh's unchallenged expertise in this area.

JLI similarly criticizes Drs. Eissenberg and Prochaska, claiming they identify "no objective standards" that restrict the use of multiple manufacturers. (JLI Mot. 5 at 16). But Drs. Eissenberg and Prochaska are not opining that JLI should have used a single manufacturer for JUULpods. Rather, they opine that the variability in nicotine delivery from the differing JUULpods impacted JUUL's abuse liability. JLI Ex. 6, Eissenberg Rpt. at 60; JLI Ex. 18, Prochaska Rpt. at 53-54. They base their opinion on their analyses of JLI's internal testing and independent analysis of ecigarettes, which certainly is within their bailiwick as leading researchers in nicotine addiction, and their own peer-reviewed published research on JUUL. Nor are Plaintiffs' experts prohibited from describing the facts underlying the differing JUULpods, such as the different manufacturers and—these are facts and they are the types of facts relied upon by experts in this field. Without this context, Dr. Eissenberg's opinion that the high-TPM JUULpods "may well lead to second wave of JUUL e-cig abuse" would have little

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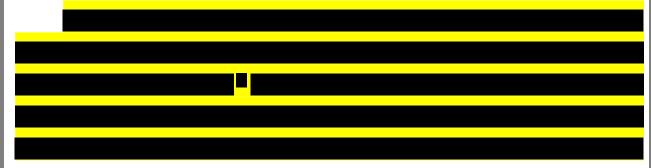
meaning. JLI Ex. 6, Eissenberg Rpt. at 147. But given the factual backdrop above, Dr. Eissenberg's

opinion is clear: high-TPM JUULpods increased JUUL's abuse liability.

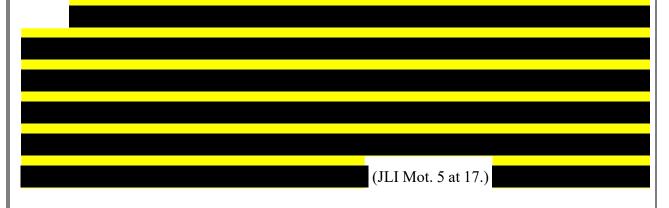
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	JLI Ex. 13, Levy Rpt. at 27; JLI Ex. 18, Prochaska Rpt. at 54; JLI Ex. 23, Shihadeh Rpt. at 18; JLI
	Ex. 25, Winickoff Rpt. at 112-115.
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	JLI Ex. 18, Prochaska Rpt. at 53-54; JLI Ex. 23, Shihadeh Rpt. at 18, 21, 37, 43.
	Finally, JLI lodges other complaints that go to the weight of Plaintiffs' experts' opinions
	and not their admissibility. For example, JLI complains that Plaintiffs' experts did not "conduct a
	study to examine how, if at all, pod variability affects actual user experience of JUUL pods." Bu
	Plaintiffs' experts don't need to conduct a study to assess the impact of fluctuating nicotine delivery
	in JUULpods on abuse liability—their training and experience affords them the expertise to make
	that determination absent a study.
	that determination absent a study.
	(III Mat. 5 at 15)
	(JLI Mot. 5 at 15).
	Hardly insignificant and certainly relevant to exper
1	testimony.

2. Whether a Specification Existed for TPM Has No Bearing on the Reliability of Opinions Related to TPM/Nicotine Spikes

Next, JLI attacks Plaintiffs' experts' opinions related to JUUL's TPM spikes. Specifically, Plaintiffs' experts opine that JLI's design of JUUL, which provides a spike of TPM in the first four-to-five puffs and allows users to recreate that spike by squeezing or flicking the JUULpod or pod-popping, increased JUUL's per-puff nicotine delivery and its abuse liability. *See* Pltf. Ex. 11, Myers Dep. 115:25-116:6, Pltf. Ex. 4, Hatton Dep. 262:6-14; *see also* JLI Ex. 6, Eissenberg Rpt. at 41-49; JLI Ex. 18, Prochaska Rpt. at 4-5, 49-51; JLI Ex. 23, Shihadeh Rpt. at 22-30; JLI Ex. 25, Winickoff Rpt. at 235. In addition, Plaintiffs' experts opine that, by permitting users to recreate the initial nicotine spike at their own schedule (which sometimes worked and sometimes did not), JUUL provides variable reinforcement thereby increasing its addictiveness. *See, e.g.*, JLI Ex. 18, Prochaska Rpt. at 54-55; JLI Ex. 23, Shihadeh Rpt. 23.



(JLI Mot. 5 at 17). This argument mimics those discussed above, and Plaintiffs' response is no different here: no objective, written standard is required for admissibility under *Daubert*.



⁸⁰ It is worth noting that Plaintiffs' experts also opine that JLI should have taken steps prior to launch to minimize nicotine spikes, such as through quality control measures and testing. JLI does not challenge these opinions.

PLAINTIFFS' OMNIBUS OPPOSITION TO DEFENDANTS' DAUBERT MOTIONS CASE NO. 19-MD-02913-WHO

1	(<i>Id.</i>).
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7	(JLI Mot. 5 at 18 <mark>)</mark>
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10	See
11	e.g., JLI Ex. 23, Shihadeh Rpt. at 18. That it did not succeed does not render expert testimony or
12	the topic inadmissible.
13	E. <u>Conclusion</u>
14	For these reasons, JLI's motion to exclude opinions on alleged failures to act should be
15	denied and the Court should not exclude: (i) expert opinions concerning JLI's alleged failure to

For these reasons, JLI's motion to exclude opinions on alleged failures to act should be denied and the Court should not exclude: (i) expert opinions concerning JLI's alleged failure to provide nicotine addiction or health risk warnings, (ii) expert opinions that JLI should have conducted additional pre-launch testing, and (iii) expert opinions that JLI should have adopted different quality control and manufacturing protocols.

X. JLI MOTION #6: ABATEMENT

JLI's criticisms of three experts' "abatement opinions" wholly lack merit. In claiming that Professors Winickoff, Kelder, and Cutler⁸¹ lack qualifications and/or used unreliable methods, JLI ignores their impressive credentials, ignores the substance and the purpose of the generic expert reports, and ignores the case schedule for expert submissions set by this Court. These well-qualified

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⁸¹ See Rule 26 Expert Witness Report and Declarations of Dr. Jonathan P. Winickoff, MD, MPH Pertains to County and City Cases, September 20, 2021; Rule 26 Expert Witness Report and Declarations of Dr. Jonathan P. Winickoff, MD, MPH Pertains to School District Cases, September 20, 2021; Rule 26 Expert Report of Steven H. Kelder, PhD, MPH, September 20, 2021; and Report of Professor David M. Cutler, September 20, 2021, respectively.

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experts have strong foundations for their abatement opinions, and any criticisms raised by JLI go to the weight of those opinions, not to their admissibility.

According to JLI, Professor Winickoff, a professor of pediatrics at the Harvard Medical School and a practicing pediatrician who has received multiple awards for his service to public health in the area of tobacco control, is unqualified to express opinions about effective treatment strategies for youth vaping and nicotine addiction.⁸² (JLI Mot. 6 at 2-3). This argument is absurd on its face.

JLI also contends that these experts' opinions are unreliable because none of them have analyzed bellwether specific data or proposed bellwether specific abatement plans in their generic reports. However, the case schedule set by the Court, and agreed to by the parties, provides for two waves of expert reports. ECF No. 2349; ECF No. 2660. On September 20, 2021, Plaintiffs' disclosed "generic" reports that, inter alia, analyzed the youth vaping epidemic at the national level and identified general strategies that would be effective in abating the epidemic of youth vaping and nicotine addiction. On January 28, 2022, consistent with the agreed-upon schedule, Plaintiffs disclosed "bellwether specific reports" that analyzed the youth vaping epidemic in each bellwether and recommended strategies to abate the epidemic in that bellwether. 83 JLI's motion is solely directed at the opinions expressed in the generic reports. The purpose of the generic reports was to provide a general framework for the bellwether specific reports. The generic reports were never intended to provide bellwether specific abatement plans or analysis, a fact that was disclosed in the reports and repeated in deposition testimony. See, e.g. JLI Ex. 54, Winickoff Dep. at 257:2-14, 262:20-263:5; JLI Ex. 12, Kelder Rpt. at n. 42; JLI Ex. 41, Kelder Dep. at 117:16-21, 122:10-17, 124:6-9; JLI Ex. 4, Cutler Rpt. at n. 3; Ex. 33, JLI Ex. 33 Cutler Dep. at 308:2-8. For this reason, JLI's arguments relating to the lack of bellwether specific abatement plans, data, or analysis, are premature and cannot support a *Daubert* challenge directed at plaintiffs' **generic** reports.

⁸² JLI does not dispute the expertise and qualifications of Professor Kelder or Professor Cutler.

⁸³ See, e.g. Rule 26 Expert Witness Report and Declarations of Dr. Jonathan P. Winickoff, MD, MPH Pertains to Wave 1 Government Bellwether: San Francisco Unified School District, California, January 28, 2022; Rule 26 Expert Report of Steven H. Kelder, PhD, MPH, Government Entity Bellwether Specific Report, January 28, 2022; Expert Report of Professor David M. Cutler, January 28, 2022.

JLI further contends that Plaintiffs' expert opinions are somehow unreliable because they rely on "public health bodies," such as the United States Surgeon General and the Centers for Disease Control. (JLI Mot. 6 at 1). This Court should reject JLI's effort to turn a clear strength of these opinions—that they are supported by large numbers of public health experts—into a weakness. At most, JLI raises an issue for cross-examination.

This Court should deny JLI's Motion No. 6 in its entirety.

A. Professor Winickoff is Highly Qualified and His Methodology is Reliable

This Court should reject JLI's efforts to exclude Professor Winickoff's "abatement opinions," based on JLI's contentions that: (1) he is not an "abatement expert," because he has not "ever designed an abatement plan for ENDS or other tobacco products," and (2) his methodology is unreliable because he does not "apply his plan to any particular entity, failed to account for recent data critical to any abatement plan, and failed to conduct any technical or scientific analysis of the school districts and municipalities at issue." (JLI. Mot. 6 at 2). Neither argument has merit.

1. <u>Professor Winickoff is Qualified to Offer Opinions Regarding Effective Abatement Strategies</u>

JLI's motion inaccurately asserts that Professor "Winickoff has no training or expertise in public policy, and he has no experience in designing or implementing public health measures for any population group." (JLI Mot. 6 at 3). This is simply wrong. In addition to being a Professor of Pediatrics at the Harvard Medical School and a practicing pediatrician with over 40,000 patient visits, Professor Winickoff is the Director of Translational Research for the American Academy of Pediatrics ("AAP"), where he translates tobacco control research into clinical practice, public policy, and real-world community strategies using tobacco control initiatives to improve youth public health. JLI Ex. 26, Winickoff Report at 2. Previously, Professor Winickoff served for seven years as the Chair of the AAP's Julius Richmond Center of Excellence Tobacco Consortium, where he led a national group of researchers to address tobacco control issues that affect children, adolescents, young adults, parents and family members. *Id.* He is also the Director of Pediatric Research at the Massachusetts General Hospital Tobacco Research and Treatment Center. *Id.* at 3. Professor Winickoff has drafted key tobacco control policy for the American Medical Association,

the AAP, and the American Pediatric Association. *Id.* at 6-7. He has testified on behalf of the AAP before numerous policymaking bodies including testimony before the U.S. Congress about JUUL specifically, the FDA about e-cigarettes and flavors, the National Academy of Medicine about raising the tobacco sales age to 21, and the Tobacco Products Scientific Advisory Committee about menthol and flavoring tobacco products. *Id.* at 7. Professor Winickoff has served as scientific advisor to the U.S. Surgeon General, the CDC, the FDA, the Department of Housing and Urban Development, the Institute of Medicine, the National Cancer Institute, the Massachusetts Tobacco Control Program, the Indiana Tobacco Control Program, the North Carolina Tobacco Control Program, and the Massachusetts Attorney General's Office. *Id.* Professor Winickoff has received numerous awards for his many contributions to public health, including the Health and Human Services Secretary's Award for Distinguished Service in "protecting the health of the United State public," the Academic Pediatric Association Health Policy Award for cumulative public policy and advocacy efforts that have improved the health and well-being of infants, children and adolescents, and the Curtis M. Hilliard Prize from the Massachusetts Health Officers Association for dedicated service and outstanding achievement in public health. *Id.* at 2.

Professor Winickoff has conducted extensive research in the area of tobacco control, including e-cigarettes. He has served as a scientific reviewer of the Surgeon General's report on Preventing Tobacco Use Among Youth and Young Adults, and as a reviewer for the U.S. Preventive Services Task Force Tobacco Use Prevention and Cessation in Children and Adolescents: A Systematic Evidence Review. Winickoff Report at 7-8. He has authored or co-authored over 150 peer-reviewed publications, including conducting studies: (a) relating to the epidemiology of e-cigarette product use in youth and young adults; (b) looking at e-cigarettes and the role of clinicians in supporting regulation and policy action; (c) looking at potential solutions to e-cigarette use among adolescents; (d) reviewing and describing the public health crisis of e-cigarettes, vapes and JUUL specifically; (e) surveying high school principals, school nurses and teachers about their awareness of e-cigarette use in their schools and what they need to address the

epidemic; and (f) looking at e-cigarette use and future cigarette initiation among never-smokers and relapse among former smokers. *Id.* at 3-5.⁸⁴

Professor Winickoff has extensive clinical experience treating youth for nicotine addiction, has conducted broad academic research into youth nicotine addiction and the youth vaping epidemic, and has helped to develop and implement policies designed to address youth vaping. This combination of clinical, academic, and policymaking experience – all of which JLI ignores – is more than sufficient to qualify Professor Winickoff as an expert regarding abatement programs to address youth vaping.⁸⁵

2. Professor Winickoff's Methodology is Reliable

Professor Winickoff's methodology for identifying potential abatement strategies is neither novel nor unusual. The Surgeon General and the CDC have documented various recommended strategies to deter youth from using tobacco products, screen for those youth that use tobacco products, and treat youth who are addicted to nicotine. The reports of the Surgeon General and the CDC carefully evaluate and analyze the efficacy of these strategies and are exactly the types of materials upon which medical professionals and policymakers routinely rely. As Professor Winickoff explained:

not qualified to opine about abating youth nicotine addiction.

⁸⁴⁸⁴ Defendants citation to *United States v. Chang*, 207 F.3d 1169 (9th Cir. 2000) and *United States v. Santini*, 656 F.3d 1075 (9th Cir. 2011) underscores the weakness of their argument. *Chang* involved exclusion of an expert with no experience identifying counterfeit securities in a case where "the only fact at issue is the authenticity" of the security. 207 F.3d at 1172-74. *Santini* involved prohibiting a psychiatrist from expressing an opinion based on data (a rap sheet) that would require interpretation by an expert in law enforcement-record keeping. 656 F.3d at 1078-79. Neither of these cases is remotely analogous to a medical expert expressing opinions about screening and treatment for youth nicotine use and addiction.

⁸⁵ JLI suggests that Professor Winickoff admitted he "lacks experience" relevant to youth tobacco abatement. Not so. At his deposition, counsel for JLI asked Professor Winickoff about implementing the recommended strategies in each bellwether jurisdiction. JLI Ex. 54, Winickoff Dep. at 252:11-19. As discussed *infra*, bellwether-specific analysis was outside the scope of the generic reports. And contrary to JLI's suggestion, Professor Winickoff testified that he had expertise in implementing similar strategies based on experience doing just that. *Id.* at 254:20-24 ("I've done a lot of implementation programs"). And Professor Winickoff's testimony that the implementation in specific jurisdictions will require coordination among experts and personnel in each jurisdiction makes perfect sense. It is a far cry from establishing that Professor Winickoff is

I was citing Surgeon General's report to represent that as the general model, as recommended by the best scientists in the county, as recommended by summaries of thousands of articles and hundreds of experts that put together those reports, so that's what I'm really relying on here is the best science that exists on the topic. I looked for other science for sure, but this here, in my estimation, in my opinion, represents the best science on this topic.

JLI Ex. 54, Winickoff Dep. at 262:8-19;⁸⁶ see also JLI Ex. 26, Winickoff Rpt. at 253 ("[T]here is consensus in both the clinical and public health communities that the abatement measures identified in this report are effective in creating a step and sustained downward trajectory of youth nicotine use and addiction."). The efficacy of these strategies has been confirmed through Professor Winickoff's extensive clinical experience screening youth for nicotine use and treating them for nicotine addiction, as laid out above. See, e.g., JLI Ex. 26, Winickoff Rpt. at 5-6 ("The opinions mentioned in this report are supported by a deep medical literature in tobacco dependence but also my own research experience"), 259 (discussing the impact of a strategy "[b]ased on [his] own prior research and clinical experience"). JLI's attacks on Professor Winickoff's methodology are nothing more than disagreements to be raised during cross examination; they are not grounds to disqualify Professor Winickoff's testimony.⁸⁷

Nevertheless, JLI criticizes Professor Winickoff for failing to "figure out the size of the population of underage users of JUUL at any particular location in the United States," and for not offering jurisdiction specific abatement plans. JLI Mot. #6 at 4, 6. As explained above, this type of

⁸⁶ Professor Winickoff has served as a reviewer for these types of reports. Winickoff Rpt. at 7-8 (discussing his service as a "Scientific Reviewer of the Surgeon General Report on *Preventing Tobacco Use Among Youth and Young Adults*" and a "reviewer for *Tobacco Use Prevention and Cessation in Children and Adolescents: A Systematic Evidence Review*").

⁸⁷ United States v. Copeland, 291 F. App'x 94 (9th Cir. 2008) and Papadopoulos v. Fred Meyer Stores, Inc., 2006 WL 1375074 (W.D. Wash. May 17, 2006) are inapposite. In Copeland, the expert was allowed to rely on the report of a non-testifying expert, but was not allowed to testify at trial regarding the substance of the report because the report was inadmissible hearsay by the non-testifying expert. 291 F. App'x at 97. Papadopoulos involved a personal injury slip and fall case where an expert's testimony was excluded because none of her opinions were based on "scientific, technical, or specialized concepts;" this is the exact opposite of Professor Winickoff's testimony regarding screening and treatment strategies for youth nicotine addiction. 2006 WL 1375074 at *2.

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jurisdiction specific analysis is beyond the scope of his generic report and is properly disclosed in bellwether specific reports. Professor Winickoff's bellwether specific reports, and the reports of other Plaintiffs' experts, none of which are challenged by this motion, perform the necessary bellwether specific analysis. *See*, *e.g.*, Pltf. Ex. 34, Winickoff San Francisco Unified School District Report (January 28, 2022) ("Winickoff SFUSD Report"). These reports evaluate the youth vaping epidemic in a particular jurisdiction, estimate the number of youth that need to be covered by the abatement remedy in that jurisdiction, and identify various strategies to be applied in that jurisdiction takin into account jurisdiction specific information. *See*, *e.g.*, *id.* at 21-40, 47-82 (discussing the number of youth who had tried e-cigarettes and currently use e-cigarettes in SFUSD on page 30).

JLI also criticizes Professor Winickoff for not performing empirical research to independently verify the effectiveness of these strategies. JLI Mot. #6 at 7. "[T]here is no per se requirement that all expert testimony be supported by empirical data." Fujifilm Corp. v. Motorola Mobility LLC, No. 12-CV-03587-WHO, 2015 WL 1737951, at *3 (N.D. Cal. Apr. 8, 2015). Moreover, as described above, Professor Winickoff relied on high quality published research on the most effective abatement strategies in combination with his clinical experience. See JLI Ex. 54, Winickoff Dep. at 262:8-19; JLI Ex. 26, Winickoff Rpt. at 253. Professor Winickoff's clinical experience, including his 40,000 patient visits, constitutes empirical observation and is a reliable basis for his opinion. See NAACP v. City of Myrtle Beach, 504 F. Supp. 3d 513, 517 (D.S.C. 2020) ("[E]xperience is the predominant, if not sole, basis for a great deal of reliable expert testimony"). As a clinician, Professor Winickoff has observed trends in nicotine addiction and youth tobacco product use in his patients. JLI Ex. 26, Winickoff Rpt. at 5. This clinical experience includes thousands of conversations he has had with his patients regarding their use of e-cigarettes and other tobacco products, as well as treating patients for nicotine addiction. That experience provides an empirical basis for his opinions regarding the effectiveness of various treatment modalities. *Id.* There is also no requirement that Professor Winickoff, or any other expert, reinvent the wheel when it comes to abatement strategies. Experts routinely rely on facts or data if that information would be reasonably relied on by other experts in their field. Daubert v. Merrell Dow Pharm., Inc., 509

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U.S. 579, 595 (1993) (citing Fed. R. Evid. 703). That is exactly what Professor Winickoff has done in considering reports by the Surgeon General and the CDC.

Finally, JLI suggests Professor Winickoff's methodology is unreliable because he allegedly failed to take into account 2021 data from the National Youth Tobacco Survey. JLI Mot. #6 at 5-6. That data was published after Professor Winickoff submitted his generic report. Still, Professor Winickoff, and Plaintiffs' other experts, address the NYTS data, and the supposed "downward trend" that it appears to show, in both their generic and bellwether specific reports. See, e.g., JLI Ex. 26, Winickoff Rpt. at 17-18 First, because of the way the survey was administered – online to both students attending school in person and those remote learning from home, the CDC, which administers the survey, has emphasized that "the 2021 NYTS estimates should not be compared with previous NYTS survey waves that were primarily conducted on school campuses." Pltf. Ex. 34, Winickoff SFUSD Rpt. at 16 (emphasis added). For example, youth that took the 2021 NYTS survey at school reported significantly higher levels of current e-cigarette use than those who took the survey at home or some other place. *Id.* at 17 (citing Pltf. Ex. 35, Park-Lee, E. et al. *Notes from* the Field: E-cigarette Use Among Middle and High School Students—United States, 2021. CDC vol. 70,39 (2021): 1387, 1387-1389 https://www.cdc.gov/mmwr/volumes/70/wr/mm 7039a4.htm ["2021 NYTS Results"]. The ostensible declines over the past two years have also occurred during the COVID-19 pandemic, a remarkable and unsettling period that saw significant restrictions imposed on the youth population, including the closure of schools, quarantines, and the severe restriction of many in-person social activities. See Pltf. Ex. 34, Winickoff SFUSD Rpt. at 16. Nothing in the data suggests that vaping rates will continue to decline, or remain the same, as COVID-19 restrictions end. Nor is it true that JUUL is no longer contributing to the youth vaping epidemic. See Pltf. Ex. 34, Winickoff SFUSD Rpt. at 18 (citing 2021 article on current state of youth e-cigarette market and the persistence of JUUL).

Moreover, even at the reduced levels suggested by the 2021 NYTS, youth vaping remains a serious problem and a public health concern. *See Id.* As Professor Winickoff explained regarding the 2020 NYTS data, while the decrease in vaping rates means that the problem appears to be not growing as rapidly, there still remains a large group of youth that are nicotine dependent and will

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require some form of evaluation and/or treatment. JLI Ex. 26, Winickoff Rpt. at 17-18. This is also true of the 2021 survey data. "In 2021, during the COVID pandemic, the NYTS still found 2.06 million middle and high school students were current users of e-cigarettes." Pltf. Ex. 34, Winickoff SFUSD Rpt. at 16. This data is particularly disturbing given that "many students were in remote learning environments that might have affected their access to tobacco products." Pltf. Ex. 35, 2021 NYTS Results; See also JLI Ex. 26, Winickoff Rpt. at 17. Furthermore, those youth who are vaping are doing so more intensely, indicating an increased likelihood of potential nicotine dependence: almost half (43.6%) of high school students reported using e-cigarettes on 20 or more of the past 30 days – up from 38.9% in 2020, and more than 1 in 4 (27.6%) high school students were using e-cigarettes every day – up from 22.5% in 2020. Compare Pltf. Ex. 35, 2021 NYTS Results with Pltf. Ex. 36, Wang, T. et. al., E-Cigarette use Among Middle and High School Students – United States. 2020. CDC vol. 69,37 (2020): 1310, 1310-1312 https://www.cdc.gov/mmwr/volumes/69/wr/ mm6937e1.htm?s cid=mm 6937e1 w. Given this, the FDA concluded that "youth e-cigarette use remains a serious public health concern amid [the] COVID-19 pandemic." Pltf. Ex. 37, Youth E-cigarette Use Remains Serious Public Health Concern COVID-19 U.S. Amid Pandemic, Food & Drug Admin. (Sept. 30. 2021), https://www.fda.gov/news-events/press-announcements/youth-e-cigarette-use-remains-seriouspublic-health-concern-amid-covid-19-pandemic. All of this underscores the significance of the 2021 NYTS data and whether an expert is properly interpreting that data is an issue for cross examination at trial. It should not serve as the basis for excluding expert testimony.

B. <u>Professor Kelder's Abatement Opinions Are the Product of a Reliable Methodology and Will Be Helpful to the Court</u>

As with Professor Winickoff, JLI fundamentally misunderstands both the purpose of Professor Kelder's generic expert report and the nature of the equitable remedy of abatement. Professor Kelder is eminently qualified to design and opine about the appropriate framework needed to abate the youth e-cigarette epidemic. A professor of epidemiology, health promotion, and behavioral science, Professor Kelder holds a PhD in Behavioral Epidemiology, a Master of Public Health in Community Health Education, and a Bachelor of Science degree in Marketing and

Economics. Economics. Economics. Economics. Economics. Editors for the 2016 Surgeon General Report, E-Cigarette Use Among Youth and Young Adults, and his ecigarette use and JUUL use prevention program, CATCH My Breath, has been shown through peerreviewed published research to be effective. JLI Ex. 12, Kelder Rpt. at 6-13. In fact, in 2017 JLI identified CATCH My Breath as among "best practice resources" for e-cigarette youth prevention. Pltf. Ex. 38, Harter Ex. DX4. Indeed, JLI does not challenge Professor Kelder's qualifications. Instead, JLI argues that his general abatement framework must be excluded because it contends Professor Kelder "fails to apply a reliable methodology, fails to fit his abatement plan to the facts of the case, and fails to undergo any technical or scientific analysis regarding the school districts and municipalities at issue." JLI Mot. #6 at 8.89 None of JLI's contentions are well-founded.

1. Professor Kelder's Abatement Framework is based on a Well-Supported, Reliable Methodology

Professor Kelder identifies six strategies that "should be implemented from a prevention perspective at the community level, including in counties, cities, and school districts." JLI Ex. 12, Kelder Rpt. at 15. These six strategies are "(1) Surveillance/Evaluation; (2) Community organization and information exchange; (3) Counter vaping mass media; (4) School and parent education; (5) Youth anti-vaping policies; and (6) Availability of cessation services." *Id.* Contrary to JLI's contention that he fails to apply a reliable methodology, Professor Kelder lays out in detail the "four widely recognized and accepted methodologies" that he uses to "provide an evidence based-model" for abatement of the youth e-cigarette epidemic. *Id.* at 57. JLI does not challenge that opinion and section of Professor Kelder's report. These methodologies are "Social Cognitive Theory," "Intervention Mapping," "Implementation Mapping," and "Diffusion of Innovation

⁸⁸ He currently serves as the Beth Toby Grossman Distinguished Professor of Epidemiology, Human Genetics & Environmental Science at the University of Texas Health Science Center at Houston, School of Public Health (UTSPH), Austin Regional Campus and a Professor in the Department of Health Promotion and Behavioral Science, also at UTSPH. JLI Ex. 12, Kelder Report at 1.

⁸⁹ JLI does not challenge Professor Kelder's opinions 1 and 2, *i.e.*, (1) that e-cigarette use in an epidemic among youth in the United States and (2) that "there are generally accepted behavioral intervention principles to design abatement strategies that will achieve their intended outcomes," which Professor Kelder details in his report. JLI Ex. 12, Kelder Rpt. at 15, 18-77.

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Theory." *Id.* at 58; *see also id.* at 59-70 (describing and explaining these methodologies). He explains that his "methodologies are proven frameworks that have been applied to address health behavioral issues like the one presented by the youth vaping and e-cigarette epidemic. These methods are considered state of the art in health promotion practice and have provided the foundation for all of [Professor Kelder's] previous school health programs, which include . . . tobacco and e-cigarette prevention and cessation." *Id.*

To design his abatement framework, Professor Kelder also considered best practices in his field, including the CDC's "Best Practices for Comprehensive Tobacco Control Programs" and "Tobacco Control Vaccine," as well as the National Institute on Drug Abuse's "16 Prevention Principles." Id. at 71-77. Using these resources, as well as his training and experience, Professor Kelder designed a general abatement framework to "implement empirically demonstrated methods successfully used to prevent combustible tobacco smoking and tailored for e-cigarettes and the contemporary political, social, and communication environments." Id. at 78; see Daubert v. Merrell Dow Pharm., Inc., 43 F.3d 1311, 1317 (9th Cir. 1995) ("That the testimony proffered by an expert is based directly on legitimate, preexisting research unrelated to the litigation provides the most persuasive basis for concluding that the opinions he expresses were 'derived by the scientific method.""). Each of Professor Kelder's strategies is well supported by the academic literature, best practices in the field of health interventions and health promotion, and his own extensive experience. See, e.g., JLI Ex. 12, Kelder Rpt. at 83 ("Surveillance is a CDC best practice for comprehensive tobacco control programs"), 88 (describing "Community-Based Participatory Research," which "is considered a best practice in health promotion planning" and citing "case studies" showing its "utility and effectiveness"), 92-93 (citing "strong evidence summarized by CDC Community Preventive Services Task Force that mass media campaigns reduce . . . youth initiation"), 98-99 (citing literature including a meta-analysis of school-based smoking prevention trials showing its effectiveness), 113 (the suggested policies are based on "proven tobacco control policies recommended by the CDC and the Community Prevention Services Task Force," as well as the Tobacco Control Vaccine), 120 (the cessation strategies are recommended by the CPSTF and the U.S. Preventive Services Task Force); see also In re Heparin Prod. Liab. Litig., 803 F.

Supp. 2d 712, 738 (N.D. Ohio 2011) ("Courts have admitted expert testimony as reliable where experts extrapolate their opinions from their knowledge and experience combined with a review of the relevant scientific literature.").

2. <u>Professor Kelder's Abatement Framework Fits This Case and Will Be Helpful to the Court</u>

Despite this plethora of scientific evidence showing that his framework will be effective in abating the e-cigarette epidemic—and is based on best practices in tobacco control—JLI contends that Professor Kelder's opinions do not fit this case because he does not tie the abatement strategies to JLI's misconduct. JLI Mot. #6 at 8. In reality, Professor Kelder does discuss JLI's misconduct when describing the need for his abatement strategies. For example, when discussing the need for counter e-cigarette mass media, Professor Kelder explained that "JUUL used media channels frequented by youth," "marketed its products towards youth-oriented groups" at sampling events, and "exposure to positive e-cigarette imagery by advertising is strongly related" to initiation of e-cigarettes. JLI Ex. 12, Kelder Rpt. at 92; *see also id.* at 100 (discussing how his school-based prevention program had to be tailored to the design features of JUUL such as nicotine salts).

But more importantly, Professor Kelder's abatement opinions need not apportion fault to particular acts of misconduct to be admissible. Professor Kelder opines on the framework needed to abate the public nuisance, the public health crisis of youth e-cigarette use that Defendants caused or contributed to. *Id.* at 14-15. As described *infra* with respect to Professor Cutler's opinions, under California law and the Restatement (Second) of Torts, Defendants may be liable for the entire harm caused this nuisance if they cannot apportion the harm caused by their conduct alone. But even if they are not liable for the entire harm, Professor Kelder's testimony is still relevant and will be helpful to the fact-finder on the issue of an appropriate remedy. *Primiano v. Cook*, 598 F.3d 558, 565 (9th Cir. 2010) ("Reliable expert testimony need only be relevant, and need not establish every element that the plaintiff must prove, in order to be admissible."); *see also Adams v. Ameritech Servs., Inc.*, 231 F.3d 414, 425 (7th Cir. 2000) ("[T]he question before us is not whether the reports proffered by the plaintiffs prove the entire case; it is whether they were prepared in a reliable and statistically sound way, such that they contained relevant evidence that a trier of fact would have

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been entitled to consider."). Judge Polster addressed a similar argument in the Opiate MDL. There, as here, "Defendants argue[d] at length that Plaintiffs' experts do not sufficiently address whether and to what extent Plaintiffs' alleged nuisance was caused by Defendants' alleged misconduct." *In re Natl. Prescription Opiate Litig.*, 1:17-MD-2804, 2019 WL 4043938, at *2 (N.D. Ohio Aug. 26, 2019). But as Judge Polster concluded, this was not a basis for excluding abatement experts: "neither Plaintiffs nor their experts need to prove their causation theories before the trial in order to present evidence on what programs, policies, and procedures will abate the opioid crisis, and what those programs, policies, and procedures will cost." *Id.* That is precisely what Dr. Kelder and all three abatement experts at issue do here: they assume that liability as to all Defendants has been established and present opinions relevant to the equitable remedy of abatement.

JLI next criticizes Professor Kelder's inclusion of youth aged through 25 in his analysis of who should be covered by the prevention program. JLI Mot. #6 at 8. Professor Kelder explained that it was appropriate to offer prevention and cessation services to youth through age 25 because nicotine is addictive and children who started using e-cigarettes under the legal age in 2015, for example, may still be addicted years later. See JLI Ex. 41, Kelder Dep. at 281:18-25 ("[I]f you are 25 years old, six or seven years ago you might have been using e-cigarettes, so the dependence carries forward."). Professor Kelder's definition of youth is therefore relevant and fits this case. Moreover, it is widely recognized in the public health community that the brains of youth under 26 are especially vulnerable to nicotine addiction. See JLI Ex. 41, Kelder Dep. at 281:15-18 ("There is a period of time before which the brain is more sensitive to nicotine and generally that's 25, 26); see also Pltf. Ex. 39, Report of the Surgeon General, E-Cigarette Use Among Youth and Young Adults at 113, 239 (Report, of which Professor Kelder was a Senior Scientific Editor, stating that "[t]he majority of tobacco users start before they are 18 years of age and almost no one starts after age 25" and discussing the vulnerability of youth and young adults under age 26 to nicotine). 90 In any event, JLI's disagreement with the scope of Professor Kelder's abatement framework is not grounds for excluding his opinion.

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⁹⁰ While Professor Kelder initially indicated he was not pulling his definition of youth from another source, he later provided the above clarification.

3. <u>Professor Kelder's Generic Report Laid Out the Framework that Can</u> Be and Was Used to Develop Bellwether-Specific Abatement Strategies

Next, JLI argues that Professor Kelder should have tailored his generic expert report to the bellwethers. JLI Mot. #6 at 9. As with Professor Winickoff, Professor Kelder's generic expert report was just that: generic and not specific to a bellwether entity. As he explained in his deposition, he reviewed the bellwether Complaints, Plaintiff Fact Sheets, and underlying documents to help him "understand and characterize what was happening in those areas." JLI Ex. 41, Kelder Dep. at 121:20-123:16. But he planned to use them, along with additional bellwether specific materials, "when the individual bellwethers abatement plan reports are due." *Id.* That is precisely what he did. In his bellwether specific report, Professor Kelder reviewed the evidence produced by the bellwethers in-depth, evaluated what each jurisdiction was already doing for prevention and what they would like to do, and explained what abatement frameworks were appropriate for them. *See*, *e.g.*, Pltf. Ex. 40, Kelder Bellwether Rpt. at 10-26, 26-30, 70-102.

Finally, JLI contends that Professor Kelder's opinions are inadmissible because he did not

Finally, JLI contends that Professor Kelder's opinions are inadmissible because he did not analyze how the bellwether entities had made use of other tobacco control funding that might be available. Judge Polster previously rejected a similar argument, holding that "testimony regarding the 'full cost of abating the public nuisance' is relevant and will help the Court understand the scope of what it will take to remedy the [] crisis. To the extent the Court determines this scope is narrowed by other programs already in place in Summit and Cuyahoga County, and/or additional sources of funding that may exist, the Court can exercise its equitable powers to deviate from the full costs of abatement to a more just and appropriate amount." *In re Natl. Prescription Opiate Litig.*, 2019 WL 4043938, at *3.91

⁹¹ JLI's citation to *General Electric Co. v. Joiner*, 522 U.S. 136, 146 (1997), is confusing as this case has no relevance to this motion. *General Electric* held that the district court did not abuse its discretion in excluding an experts' opinion "because it was within the District Court's discretion to conclude that the studies upon which the experts relied were not sufficient, whether individually or in combination, to support their conclusions." *Id.* at 146-147. JLI does not identify any evidence Professor Kelder relied on that was not sufficient to support his conclusions. Similarly, JLI cites *Nationwide Transport Fin. v. Cass Info. Sys., Inc.*, 523 F.3d 1051, 1060 (9th Cir. 2008), which again, appears irrelevant. In the section of the case cited by the JLI the Court holds only that it was not error to exclude testimony that amounted to a legal conclusion because the District Court

C. Professor Cutler's economic opinion that there are substantial costs to communities associated with the youth vaping epidemic are entirely appropriate and relevant.

JLI's arguments regarding Professor Cutler fall equally flat. While JLI's own citations to Professor Cutler's deposition testimony make clear that he is not offering any opinions regarding an appropriate abatement plan (JLI Mot. #6 at 11), JLI nevertheless contends his "abatement plan" must be excluded because it "does not fit the facts of the case" and fails to "account for critical information relevant to abatement[.]" *Id.* at 10-11. These arguments reflect a fundamental misunderstanding of the scope of Professor Cutler's opinions, and come nowhere near meeting the standards justifying exclusion under *Daubert*. 92

First, as JLI acknowledges, Plaintiffs retained Professor Cutler to cost the components of an abatement plan, and specifically for the six Wave 1 bellwether jurisdictions. As he made clear in his September report, that quantification—along with other opinions—would be forthcoming in his January 28, 2022 jurisdiction-specific reports:

In a separate report to be submitted at a later date, I have also been asked to evaluate: (a) whether the actions of JUUL and Altria have had a causal impact on the use of vaping products by youth in King County, Washington; the San Francisco Unified School District, California; the School District of Palm Beach County, Florida; Tucson Unified School District, Arizona; Goddard Unified School District, Kansas; and the City and School District of Rochester, New Hampshire; and if so, (b) what harms in these areas can be attributed to JUUL and Altria; and (c) what levels of spending would be needed to abate the youth vaping epidemics occurring in these areas.

JLI Ex. 4, Cutler Report, ¶ 7, FN 3 (emphasis added). As JLI acknowledges, Professor Cutler is not opining on whether particular abatement plans are appropriate; rather he is quantifying their cost.

JLI Mot. #6 at 11. That is what Professor Cutler did in the most recently disclosed January 28, 2022

permitted the expert to testify regarding the circumstances that led him to formulate his opinion. *Id.* JLI identifies no impermissible legal conclusions being offered by Professor Kelder.

⁹² As set forth in the Plaintiffs' Opposition to JLI's Marketing *Daubert* Brief, Professor Cutler is one of the nation's leading health economists and is eminently qualified to provide opinions regarding the costs and impacts of the youth vaping epidemic. *See* Section V.B.2.k.Indeed, Professor Cutler regularly studies and analyzes the impact of addictive goods to the subsequent harms they cause to society. *Id*.

report, in which he submitted opinions regarding the costs associated with abating the youth vaping epidemic in the six specific bellwether jurisdictions based on, inter alia, inputs from Drs. Winickoff and Kelder. Thus, JLI's arguments challenging Professor Cutler's "abatement plan" can be rejected on this basis alone.⁹³

Second, JLI's argument that Professor Cutler's "estimate" of the abatement plan should be excluded is similarly misplaced. To be clear, one of Professor Cutler's eight opinions in his September report concludes to a reasonable degree of professional and economic certainty that:

> Youth use of JUUL in the past few years has created a number of problems for school districts, counties, and cities. These include increased costs of anti-vaping and nicotine programs, increased costs of monitoring and disciplining on-campus vaping, greater classroom disruptions and difficulties teaching, and decreased student learning. Substantial abatement efforts will be required to address and reverse the youth vaping epidemic.

JLI Ex. 4, Cutler Rpt., ¶ 8 (emphasis added). To support this opinion, Dr. Cutler provides examples of costs incurred by these communities and jurisdictions due to youth JUUL use and the youth vaping epidemic. *Id.*, ¶ 37-56. Professor Cutler further establishes that substantial abatement efforts will be required because the CDC concluded in its Best Practices for Comprehensive Tobacco Control Programs more than eight years ago in 2014 that the national cost of a comprehensive tobacco-control program would be \$3.3 billion annually. *Id.*, ¶¶ 87-95. Professor Cutler adjusted these numbers into today's dollars by adjusting for inflation and population growth, and applied a higher youth nicotine usage rate. Id., ¶¶ 93-94. These calculations, which are reflected in Exhibit 15 of Professor Cutler's report and go unchallenged by JLI, serve illustrate the widely accepted fact that an abatement program to mitigate the impacts of nicotine addiction would be extremely expensive. This opinion unequivocally assists the trier of fact in understanding the efforts required to mitigate and ultimately abate the problems created by the youth vaping epidemic.

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Third, and relatedly, Professor Cutler's reliance on the CDC's Best Practices for Comprehensive Tobacco Control Programs is perfectly appropriate. As set forth above, this particular CDC report is "based upon information and experience derived from state practices, scientific studies, and input from external partners and experts in the field of tobacco control." Pltf. Ex. 41, CDC, Best Practices for Comprehensive Tobacco Control Programs at 24 (emphasis added). Thus, Professor Cutler's specific reliance on the costing components of the 2014 CDC Report for his opinion regarding the substantial costs of an abatement program is a sufficient and reasonable methodology to base his opinion upon. See Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579, 593 (1993) ("[S]ubmission to the scrutiny of the scientific community is a component of 'good science'" and "widespread acceptance can be an important factor in ruling particular evidence admissible"); see also Deutsch v. Novartis Pharms. Corp., 768 F.Supp.2d 420, 431 (E.D.N.Y.2011) (Expert opinion is admissible if it is based on 'good grounds, based on what is known.").

Finally, JLI's argument that Professor Cutler's abatement opinion apportion a specific amount to JLI's misconduct misconstrues Professor Cutler's assignment. One of the questions presented to Professor Cutler was: "Can the youth vaping epidemic be addressed? If so, how, and at what cost?" JLI Ex. 4, Cutler Rpt., ¶ 7. He was never asked to opine on what proportion of the harm can be attributed to JLI alone, and rightfully so, as his expert report ultimately establishes that both JLI and Altria were causally responsible for the increase in youth vaping rates. His report further establishes that from an economic perspective, multiple wrongdoers can contribute to the same indivisible harm. *Id.*, ¶¶ 82-87. This analysis is consistent with public nuisance law and the equitable remedy of abatement. Once liability is established, defendants are jointly and severally liable for addressing the nuisance they created:

Where several persons act in concert and damages result from their joint tort, each person is held for the entire damages unless segregation as to causation can be established. Even though persons are not acting in concert, if the result produced by their acts are [sic] indivisible, each person is held liable for the whole. . . . The reason for imposing liability on each for the entire consequence is that there exists no basis for dividing damages and the law is loath to permit an innocent plaintiff to suffer as against a wrongdoing defendant.

Finnegan v. Royal Realty Co., 35 Cal. 2d 409, 433–34, 218 P.2d 17, 32 (1950). Indeed, where the "harm resulting from a nuisance is not capable of apportionment to the several contributors upon any reasonable or rational basis." Rest.2d. Torts, § 840E, com. c. Defendants, and not the plaintiff, bear the burden of producing evidence upon which an apportionment could be made. Rest.2d Torts, § 840E, com. b. Thus, Professor Cutler's expert opinion regarding the cost of abatement due to the youth vaping epidemic as a whole assists the trier of fact in understanding what the potential costs may ultimately be, a quantification Professor Cutler specifically undertook in his most recent January report.⁹⁴ To the extent JLI has concerns with Dr. Cutler's calculations, it may raise those on cross-examination.

Ultimately, Professor Cutler—one of the nation's leading health economists who regularly examines causal relationships between addictive goods and subsequent harms—opines that there are substantial costs associated with addressing the harms caused by JLI's misconduct. This economic perspective undoubtedly assists the trier of fact in understanding what those costs could be, and JLI presents no basis to exclude any of Professor Cutler's opinions related to abatement.

D. <u>Conclusion</u>

to the bellwether specific reports.

This Court should reject JLI's Motion #6 in its entirety.

XI. ALTRIA MOTION

Altria's "targeted" motion is anything but. Selectively quoting depositions and misinterpreting or misconstruing the methodologies, opinions, and qualifications of Plaintiffs' experts, Altria asks this Court to exclude often unspecified testimony from Drs. Drumwright, Eissenberg, Grunberg, Jackler, Pratkanis, Shihadeh, Winickoff, and Prochaska. These challenges are based on disagreements with these expert's reliable methodologies or critiques of their specific qualifications and go to weight, not admissibility. As explained below, the issues Altria raises are

⁹⁴ To the extent JLI has arguments regarding Professor Cutler's opinions in his January 28, 2022

report, they obviously are free to do so pursuant to the agreed-upon *Daubert* deadlines with respect

⁹⁵ For Drs. Eissenberg and Shihadeh, Plaintiffs have withdrawn their Altria-specific opinions, and therefore, those arguments will not be addressed *infra*.

appropriately dealt with through cross-examination, introduction of Altria's own evidence, and testimony from their competing experts, not exclusion.

A. <u>Dr. Drumwright Applies a Reliable Methodology in Evaluating Altria's Impact on JUUL Sales and Youth Access⁹⁶</u>

Altria seeks to exclude Dr. Drumwright's causation opinions, claiming that she performed "no analysis whatsoever" in evaluating Altria's impact on JUUL sales and youth access (Altria Mot. at 2, 9-10), failed to identify precise percentages and numbers as to how much Altria's actions impacted JUUL sales and youth access (Altria Mot. at 3), and failed to rule out other potential causes of JUUL's increased sales and youth access (Altria Mot. at 10).

First, an examination of the record reveals that Dr. Drumwright's causation opinions are not "speculative assumptions untethered to any analysis of data." Altria Mot. at 2. Dr. Drumwright's analysis involved synthesizing the information reported by JLI, Altria, and the Surgeon General (among others), which Altria misconstrues by selectively quoting from her deposition. JLI Ex. 34, Drumwright Dep. 288:4-8 ("I think it's my job to take all the materials that I see, read them, interpret them, analyze them, synthesize them, and then come up with an opinion."), 34:16-23, 373:5-374:9, 375:15-376:6.; JLI Ex. 5, Drumwright Rpt. 157-68. This is a reasonable methodology. Fed. R. Evid. 703 ("An expert may base an opinion on facts or data in the case that the expert has been made aware of or personally observed."); *In re Bard IVC Filters Products Liab. Litig.*, MDL 15-02641-PHX DGC, 2017 WL 6554163, at *2 (D. Ariz. Dec. 22, 2017) (Defendants internal "documents are factual evidence in this case, and experts clearly are permitted to take factual evidence into account." (citing *Weinstein's Federal Evidence* § 703.04[3] (experts may rely on interviews, reports prepared by third parties, clinical and other studies, business, financial, and accounting records, and general knowledge or experience))). Notably, Altria does not claim these sources are somehow unreliable or are otherwise inappropriate to rely

⁹⁶ Altria's Motion contains a (1) "Background" section that identifies the experts its challenging on an expert-by-expert basis and an (2) "Argument" section that largely lumps the experts together. For purposes of efficiency, Plaintiffs address Altria's arguments on an expert-by-expert basis. *See Sanchez v. Boston Sci. Corp.*, 2:12-CV-05762, 2014 WL 4851989, at *5 (S.D.W. Va. Sept. 29, 2014) ("Rule 702, by its plain terms, contemplates *Daubert* challenges directed at the opinions of specific experts, not the opinions of a collection of experts.).

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upon nor does Altria claim that Dr. Drumwright's methodology is otherwise unreliable. And that is because her methodology is sound—Dr. Drumwright uses principles common within the field, such as: increased distribution increases sales, which, in the context of a youth vaping epidemic, increases youth access to the product. JLI Ex. 34, Drumwright Dep. 376:1-13, 383:2-9, 386:8-15. Her decision not to rely on a particular source, *see Id.* 376:1-6, or perform the exact analysis demanded by Altria, goes to weight, not admissibility, of her testimony. *See In re Packaged Seafood Prod. Antitrust Litig.*, No. 15-MD-2670 JLS (MDD), 2020 WL 5739316, at *4 (S.D. Cal. Sept. 24, 2020).

Altria next criticizes Dr. Drumwright for not knowing exact percentages and numbers related to Altria's impact on JUUL sales, including sales to youth and sales attributable from specific marketing campaigns, like Make the Switch. Altria Mot. at 3, 11. But this type of certainty is not required under *Daubert*. *See Primiano v. Cook*, 598 F.3d 558, 565 (9th Cir. 2010) ("Lack of certainty is not, for a qualified expert, the same thing as guesswork.").

JLI Ex. 5, Drumwright Rpt. at 161, 163, 165-

168; JLI Ex. 34, Drumwright Dep. 356:14-21, 367:2-10, 367:21-368:10, 372:15-17, 382:9-17, 383:2-9, 384:6-22. These opinions are given with a reasonable degree of certainty, are based on evidence and logic, and are not speculative. JLI Ex. 5, Drumwright Rpt. at 1.

Finally, Dr. Drumwright does not need to "rule out" other possible causes for her opinion on causation to be admissible. To be admissible, an expert's methods need only "fall[] within the range of accepted standards" that govern his or her field of expertise. *See Daubert v. Merrell Dow Pharms.*, *Inc.*, 43 F.3d 1311, 1317 (9th Cir. 1995) [*Daubert II*]. And while the acceptable standard for a medical doctor's differential diagnosis includes considering and ruling out other causes of harm, see Id. at 1319, JLI offers no explanation of why this standard is required for Dr. Drumwright or any other expert not giving a medical diagnosis, particularly when the facts underlying the opinions—such as the fact that Altria knew JUUL was causing a youth vaping epidemic and that Altria expanded JUUL's sales and distribution anyway—

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Drumwright Rpt. at 158 (Willard), 165 (Gifford); *In re Toyota Motor Corp. Unintended Acceleration Mktg., Sales Practices, and Products Liab. Litig.*, 978 F. Supp. 2d 1053, 1070 (C.D. Cal. 2013) ("[A]rguments about other sources that [the expert] could have consulted . . . and alternative explanations [s]he could have considered . . . go to weight, not admissibility.").

B. <u>Dr. Grunberg is Qualified to Render Opinions Related to Altria's Conduct</u> and his Opinions are Based on Sound Methodology

Dr. Grunberg is a Professor of Medical and Clinical Psychology, a Professor of Neuroscience, and a Professor of Military and Emergency Medicine at the Uniformed Services University of the Health Science (USU) in Bethesda, Maryland. JLI Ex. 8, Grunberg Rpt. at 1.97 He specializes in nicotine and tobacco use, addiction, and behavioral health. *Id.* He literally wrote the book on nicotine addiction, serving as writer and scientific editor of the landmark 1988 Surgeon General Report entitled *Nicotine Addiction. Id.* His conclusions remain authoritative and have been cited in every subsequent Surgeon General Report on tobacco and health, including the 2020 Report on *Smoking Cessation.* Dr. Grunberg also has four decades of experience researching and publishing articles on nicotine, youth addiction, and the tobacco industry, which make him highly qualified to offer his opinions in this case. *Id.* at 4-9. Unsurprisingly, Dr. Grunberg has been repeatedly qualified as an expert in litigation involving dangers of nicotine products. *Mash v. Brown & Williamson Tobacco Corp.*, 4:03CV0485TCM, 2004 WL 5537079, at *3 (E.D. Mo. Aug. 2, 2004) (denying *Daubert* motion against Dr. Grunberg and recognizing that his career has been "focused on the dangers and dependence of cigarette smoking").

Numerous courts have recognized that, Dr. Grunberg is qualified to testify "concerning cigarette advertising and marketing" given his education and training as a social psychologist with "expertise on the social forces that influence a smoker's tobacco use" and his vast experience with "campaigns to prevent smoking." *See, e.g., Dover v. R.J. Reynolds Tobacco Co.*, 3:09-CV-11531 SAS, 2014 WL 4723116, at *6 (M.D. Fla. Sept. 22, 2014); *see also Burton v. R.J. Reynolds Tobacco Co.*, 183 F. Supp. 2d 1308, 1316 (D. Kan. 2002) (denying *Daubert* motion and permitting

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⁹⁷ He is also a Professor in the USU Graduate School of Nursing and has provided consultations to a wide range of government and non-governmental organizations on nicotine addiction, tobacco use, and behavioral health.

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Dr. Grunberg to testify about the tobacco industry's knowledge of the harmful effects of nicotine); *Berger v. Philip Morris USA Inc.*, 309CV14157WGYHTS, 2014 WL 10715266, at *4 (M.D. Fla. Aug. 29, 2014) (permitting Dr. Grunberg's testimony against Altria's subsidiary – Phillip Morris USA – regarding his analysis of "internal company documents, opinions on cigarette design, and cigarette advertising and marketing.").

Setting aside his qualifications, experience and prior Court's determinations to the contrary, Altria alleges that Dr. Grunberg "lack[s] any degree, training, or experience in marketing, supply chain management, or any other subject that would render [him] capable of determining whether the Altria Defendants' conduct caused an increase in JUUL sales or use by underaged users." Motion at 11-12. But Dr. Grunberg is well-qualified to testify regarding conduct that would cause a rise in sales of a nicotine product among youth use given his doctorate degree and training in social psychology, a discipline which applies relevant principles related to marketing to youth, such as persuasive communication, peer modeling, social influence, and other useful principles. JLI Ex. 8, Grunberg Rpt. 37-42; JLI Ex. 37, Grunberg Dep. at 109:4-10.

The sole opinion offered by Dr. Grunberg that is specifically challenged in Altria's brief is that "JLI's advertising and marketing strategy, which was facilitated by Altria, is attractive and appealing to youth and nonsmokers." Mot. at 5; JLI Ex. 5, Grunberg Rpt. at 3. Altria contends he performed "no analysis" to reach this opinion. Mot. at 5. As an initial matter, this misconstrues Dr. Grunberg's testimony; he did not testify that he performed "no analysis" to reach his opinions as represented in Altria's brief. Mot. 4. Rather, he stated that he did not perform an "empirical analysis" of the impact of Altria on JUUL's sales, which he defined as: "an independent fiduciary, financial, or market analysis." JLI Ex. 37, Grunberg Dep. at 400:6-21. "[T]here is no per se requirement that all expert testimony be supported by empirical data." Fujifilm Corp. v. Motorola Mobility LLC, 12-CV-03587-WHO, 2015 WL 1737951, at *3 (N.D. Cal. Apr. 8, 2015). Dr. Grunberg instead relied on his significant experience in social psychology and the impact of

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⁹⁸ It was unclear in Dr. Grunberg's deposition what defense counsel meant by empirical. *See* Grunberg Tr. 14:6-15:19 ("So you'd have to explain what you mean by "empirical data" because that can have several meanings"), 34:23-35:13 ("because you would not define empiricism, . . . for the record, I want to keep restating, I'm not sure what you mean by 'empiricism'").

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tobacco marketing and his review of tobacco industry and Defendants' documents and scientific literature to opine that JLI and Altria were on notice that the marketing strategies used by JLI have been demonstrated to appeal to youth and encourage smoking and nicotine consumption. See JLI Ex. 8, Grunberg Rpt. at 102-106. Dr. Grunberg's methodology is grounded in: (1) his training and education in the aspects of social psychology that are relevant to marketing, see JLI Ex. 8, Grunberg Rpt. 137-38, and (2) the application of his decades of experience and knowledge researching the tobacco industry's efforts to addict youth through flavors and specialized marketing that "exploited [young people's] associative learning and conditioning process to present the image of tobacco cigarettes positively." JLI Ex. 8, Grunberg Rpt. App. 4.

Based on this highly relevant combination of expert qualifications, Dr. Grunberg could and did conclude that Altria knew that JLI employed the youth marketing strategies to great effect in capturing the youth market for nicotine. JLI Ex. 8, Grunberg Rpt. 2-3; Grunberg Rpt. App. 37. By drawing on informed comparisons based his experience studying tobacco and nicotine addiction, Dr. Grunberg then confirmed through review of case documents that Altria "facilitated" JLI's marketing strategy by implementing several big tobacco youth marketing strategies, including: (1) JLI Ex. 37, Grunberg Dep.

at 391:1-4; JLI Ex. 8, Grunberg Rpt. 122; (2)

JLI Ex. 37, Grunberg, Dep. at 398:18-25; JLI Ex. 8,

Grunberg Rpt. at 122-25, and (3)

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JLI Ex. 8, Grunberg Rpt.

at 29, 96-97. Dr. Grunberg's testimony is based on his extensive knowledge and experience and a reliable methodology and is therefore admissible.

C. Dr. Jackler is Qualified to Render Opinions Related to Altria's Conduct and his Opinions are Based on Sound Methodology

Dr. Jackler has spent more than 15 years studying tobacco industry marketing, and he is the founder of the research group Stanford Research into the Impact of Tobacco Advertising (SRITA). Jackler Report at 8. SRITA is part of the Stanford Tobacco Research Collaborative (STRC), which Dr. Jackler also founded. *Id.* SRITA has created the largest repository of tobacco advertising imagery in the world. *Id.* Nevertheless, Altria argues that Dr. Jackler is not qualified to testify because he does not have a degree in marketing and has not worked in marketing or supply chain management. This argument misapplies FRE 702 and overlooks Dr. Jackler's vast experience and training. *See Rogers v. Raymark Industries, Inc.*, 922 F.2d 1426, 1429 (9th Cir. 1991) ("[A] witness can qualify as an expert through practical experience in a particular field, not just through academic training.").

Dr. Jackler's expertise in tobacco marketing research and its effects on the public has been recognized in myriad scholarly publications and by numerous universities, health organizations, regulatory bodies, and Congress. *Id* at 8-10. Before his testimony at the July 2019 House Oversight Committee hearing, Examining JUUL's Role in the Youth Nicotine Epidemic, Committee Chairman Hon. Raja Krishnamoorthi introduced Dr. Jackler as "the preeminent tobacco advertising scholar in the country." Examining JUUL's Role in the Youth Nicotine Epidemic: Part I: Hearing before the Subcomm. on Economic and Consumer Policy, 116 Cong. 51 (2019) (Introductory Remarks from Hon. Raja Krishnamoorthi). Dr. Jackler, therefore, is more than qualified to provide marketing opinions in this case.

Defendants also argue Dr. Jackler's testimony is inadmissible because he opines Altria "provided services to help JUUL increase its growth and sales and ultimately put more JUUL products, including mint products, into retail stores" without offering regression analyses or calculations as proof. But regressions and calculations are not required: internal documents and testimony establish that in conjunction with its investment in JLI, Altria provided JLI access to its marketing, distribution, and sales infrastructure. JLI Ex. 11, Jackler Rpt. at 425-430 (citing deposition of Altria CEO William Gifford at 180)

United Food & Com. Workers Loc. 1776 & Participating Emps.

Health & Welfare Fund v. Teikoku Pharma USA, 296 F. Supp. 3d 1142, 1194 (N.D. Cal. 2017) (An

expert "of course, [is] allowed to identify the facts (documents, testimony) that support his otherwise permissible opinions. Defendants are free to challenge [the expert] on the stand regarding his interpretations of those documents and testimony.").

JLI Ex. 11, Jackler Rpt. at 426-27. Dr. Jackler then reviewed the academic literature about the impact of tobacco products on shelf space, referred to as the tobacco "powerwall," and concluded that "[r]esearch shows these visually impactful displays contribute to adolescent use of tobacco products." *Id.* Dr. Jackler's expertise in this field will aid the jury in understanding Altria's partnership with JLI and the significance of that partnership in the landscape of an epidemic.

When Dr. Jackler wrote and testified that Altria contributed to JLI's sales growth he was basing his opinion on his review and analysis of documents and deposition testimony from the Defendants. JLI Ex. 40, Jackler Dep. at 316:7-21; JLI Ex. 11, Jackler Rpt. at 422-431. Dr. Jackler formed this opinion using established facts and the research methods he has developed through decades studying tobacco marketing. If Altria believes he is incorrect, they can challenge this opinion on cross examination. *Messick*, 747 F.3d at 1199.

D. <u>Dr. Pratkanis is Qualified to Render Opinions Related to Altria's Conduct and his Opinions are Based on Sound Methodology</u>

Altria is mistaken about Dr. Pratkanis' qualifications. As outlined in his report, Dr. Pratkanis has significant experience in marketing, including teaching courses in "marketing management, buyer behavior, and advertising" at Carnegie-Mellon University. JLI Ex. 17, Pratkanis Rpt. at 1. He has also presented and published on marketing throughout his career and served on the editorial board of the Journal of Public Policy and Marketing, among many other relevant journals. Altria also misunderstands the expertise Dr. Pratkanis holds as a social psychologist. 99 Dr. Pratkanis specializes in social influence and belief formation, including mass

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⁹⁹ Dr. Pratkanis holds a Ph.D. in social psychology and serves as an Emeritus Professor of Psychology at the University of California Santa Cruz. JLI Ex. 17, Pratkanis Rpt. at 1.

communications and sales practices. Id. Social influence analysis is an approach used to "understand how a consumer is influenced and persuaded by marketing and other communications" and describe "how the marketing communication is likely to impact the target." Id. at 4. This experience is highly relevant and qualifies Dr. Pratkanis to offer the opinions in his report concerning Altria.

Altria challenges three statements by Dr. Pratkanis: (1) Altria "significantly increased distribution and availability of JUUL, further fueling the youth nicotine epidemic;" (2) Altria "misled smokers that JUUL was a device for quitting nicotine;" and (3) Altria played a "key role" is disseminating the "'Make the Switch' message." Altria Mot. at 6. To reach these conclusions, Dr. Pratkanis reviewed and assessed a wide range of documents and based his findings and conclusions on the "scientific work in the field of consumer behavior and the related field of the science of social influence" and his more than 35 years of knowledge, training, and experience as an expert. JLI Ex. 17, Pratkanis Rpt. at 2.

As to the first challenged opinion, Dr. Pratkanis concluded that: "In 2018, in the midst of a

severe and rapidly growing youth nicotine epidemic, JLI consummated a deal with Altria . . . and together JLI and Altria significantly increased distribution of JUUL (), thereby making JUUL even more widely available and further fueling the youth nicotine epidemic." JLI Ex. 17, Pratkanis Rpt. at 110. As explained in his report, he determined that the evidence shows that JUUL was causing an epidemic of youth nicotine addiction and demand for JUUL product outstripped supply, that Altria knew this , and that Altria expanded the distribution and sales of JUUL. See, e.g., JLI Ex. 17, Pratkanis Rpt. at 96-99, 108. As part of this analysis, Dr. Partkanis described how the "Tobacco Power Wall," i.e. the "display of nicotine products in retail stores" which Altria helped JLI increase, played an important role in sales of tobacco products to youth: "Prominent shelf space at retail outlets is particularly important for selling nicotine products to youth through the tobacco power

Dr. Pratkanis then explained Altria's role in expanding distribution and sales, "including closing

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tens of thousands of distribution gaps and increasing JUUL sales in one month along by over 200,000 cartons" and "markedly increased shelf space." *Id.* at 99, 110. Given his analysis regarding the role of JUUL in causing the youth epidemic and the part played by the Tobacco Power Wall in attracting youth and his review of the documents showing Altria's role, Dr. Pratkanis was able to conclude that Altria's actions in increasing JUUL's sales for JUUL products further fueled the epidemic. Altria's challenges that he should have conducted an empirical analysis to analyze the impact of its actions go to weight, not admissibility. *See Fujifilm Corp.*, 2015 WL 1737951, at *3.

The other two challenged opinions regarding Altria's misleading of smokers and the Make the Switch campaign are also based on sound methodology and are helpful to the jury. First, Dr. Pratkanis explained what his review of documents shows about Altria's role

. JLI Ex. 17, Pratkanis Rpt. at 42. Then, he analyzed the Make the Switch campaign that Altria distributed and explained the misleading "health and safety message" the campaign was sending to consumers, including that JUUL was a device for quitting nicotine. *Id.* at 42-52 ("Using Grice's principles, a reasonable consumer would take away a health message from these slogans" used in the Make the Switch campaign and to a consumer, "switching to JUUL is seen as the equivalent of stopping smoking"). Dr. Pratkanis also explained the impact of messaging including in this campaign on youth, such as the fact that "by portraying JUUL as an alternative for adult smokers, the product becomes more attractive to youth who are seeking independence and adulthood." *Id.* at 51. Altria's focus on quantifying the impact of this campaign on youth sales misses the point: in this portion of Dr. Pratkanis' report, he uses his experience in marketing and consumer perceptions to evaluate the message communicated to consumers by Altria and JLI through this campaign, he is not attempting to quantify the direct impact of this campaign on sales to youth.

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E. <u>Dr. Prochaska is Qualified to Render Opinions Related to Altria's Conduct and her Opinions are Based on Sound Methodology</u>

Dr. Prochaska is a Professor of Medicine with the Stanford Prevention Research Center in the Department of Medicine and the School of Medicine at Stanford University and a practicing clinical psychologist with a specialty in nicotine addiction and experience treating patients addicted to JUUL. JLI Ex. 18, Prochaska Rpt. at 1. Despite Altria's claim that she does not have specialized training in marketing, Dr. Prochaska has spent her career studying the impact of tobacco use and marketing and how to help smokers quit and serves as a faculty member of the Standard Research into the Impact of Tobacco Advertising (SRITA) collaborative, which studies the effects of tobacco advertising, marketing, and promotion. *Id*.

She also has significant experience in tobacco control and prevention, including as the

She also has significant experience in tobacco control and prevention, including as the Faculty Director for Stanford's Master of Science Program in Community Health and Prevention Research and has spent years studying "tobacco product marketing, tobacco polices, and mass media tobacco control campaigns," along with "cigarette design and tobacco industry documents." *Id.* Tobacco control is the field of prevention of tobacco use and exposure in children and families and promotion of cessation in adolescents and adults who use tobacco. *See Tobacco Control and Prevention*, American Academy of Pediatrics, https://www.aap.org/en/patient-care/tobacco-control-and-prevention/ (last accessed January 26, 2022). This field of study requires deep knowledge of factors driving youth initiation of tobacco products, including tobacco marketing and the other actions of tobacco companies in driving youth use. *Id.* Dr. Prochaska has published over 250 peer-reviewed publications relevant to her opinions in this case, including publications on tobacco marketing and e-cigarettes, and has consulted with the Federal Trade Commission in their consumer division on deceptive advertising practices. *Id.* She was even approached to consult for JLI as a scientist and expert witness in litigation. *Id.* She has testified in dozens of

¹⁰⁰ Dr. Prochaska's research has earned her awards from the National Institute on Drug Abuse and the Society for Research on Nicotine and Tobacco. She is also a "past-President and Fellow of the Society for Research on Nicotine and Tobacco, the international scientific society aimed at stimulating the generation and dissemination of new knowledge concerning nicotine and tobacco from bench to bedside and through to health policy." *Id.* at 1-2.

tobacco cases on matters including tobacco product use and addiction, consumer knowledge and risk perceptions relating to smoking and vaping nicotine, tobacco product marketing influences on smoking and vaping behaviors, and tobacco industry documents and conduct. *Id.* at 3. Dr. Prochaska based her opinions on her more than 20 years of experience and expertise in the tobacco control field, including her review of JUUL and tobacco industry documents. *Id.*

by Defendants' conduct in design, marketing, flavoring, promoting, selling, and manufacturing

JUUL. Altria Mot. at 7. This opinion is grounded in her review the evidence regarding Altria's

actions, her training and experience with tobacco control and marketing, and her experience with

Altria challenges Dr. Prochaska's opinion that B.B.'s addiction was initiated and sustained

nicotine addiction. See JLI Ex. 18, Prochaska Rpt. at 3. Based on her extensive experience with nicotine addiction, Dr. Prochaska opined that "[e]very JUULpod that [B.B.] consumed contributed to sustaining her addiction." JLI Ex. 19, Prochaska B.B. Rpt. at 12. She explained how the evidence and literature showed that Altria had substantial evidence that JUUL was attracting youth, JLI Ex. 18, Prochaska Rpt. at 76-83, and nevertheless expanded JUUL's sales and distribution, assumed a significant role in JLI's leadership, and did not assist JLI with youth prevention, Id. at 5-6, 85-89. Far from being just "ipse dixit," Dr. Prochaska cited evidence in the record supporting her opinions. JLI Ex. 18, Prochaska Rpt. at 5, 85-89 (citing documents); see Jensen v. American Medical Systems, 2021 WL 6139631, at *5 (E.D. Wash. Apr. 30, 2021) (expert's methodology reliable where "he has reviewed deposition materials; [...] medical records;

Dr. Prochaska also opined based on her extensive knowledge of tobacco control and the impact of tobacco marketing, that these actions were irresponsible given the broader history of tobacco control and Marlboro's own appeal to youth and Altria's knowledge of JUUL's intense youth appeal. *See Id.* at 86-90 (citing evidence); Fed. R. Evid. 702, Advisory Committee Note (2000) (recognizing that "application of extensive experience" to the facts of the instant case is a proper methodology). Altria's challenges to Dr. Prochaska's reliable methodology and the support for her opinions go to weight, not admissibility. *See Hangarter v. Provident Life and Acc. Ins. Co.*,

scientific literature; [and] corporate documents from Defendant [...] in forming his opinions.").

373 F.3d 998, 1017 (9th Cir. 2004) (For non-scientific testimony, "reliability depends heavily on the knowledge and experience of the expert, rather than the methodology or theory behind it.").

Finally, Altria contends that Dr. Prochaska did not connect the actions of Altria directly to B.B.'s use of JUUL. Altria Mot. at 8. First, evidentiary connection Altria's actions directly to B.B. is not required, as explained in Plaintiffs' Opposition to Altria's Motion for Summary Judgment. But even if Plaintiffs did have to make that direct connection, Dr. Prochaksa does not. "Reliable expert testimony need only be relevant, and need not establish every element that the plaintiff must prove, in order to be admissible. *Primiano v. Cook*, 598 F.3d 558, 565 (9th Cir. 2010); *see also* Manual of Model Civil Jury Instructions for the District Courts of the Ninth Circuit (explaining that "the law makes no distinction between the weight to be given to either direct or circumstantial evidence).

F. <u>Dr. Winickoff is Qualified to Render Opinions Related to Altria's Conduct and his Opinions are Based on Sound Methodology¹⁰¹</u>

Dr. Winickoff is a pediatrician at Massachusetts General Hospital and a Professor of Pediatrics at Harvard Medical School, and holds degrees in Biopsychology from Yale University, an M.D. from Harvard Medical, and a Master of Public Health from the Harvard School of Public Health. JLI Ex. 25, Winickoff Rpt. at 2, 9. Dr. Winickoff has extensive experience, both through academic research and his more than twenty years in practice, with tobacco control and the impact of tobacco company marketing and promotion. *Id.* at 2-9. Like Dr. Prochaska, Dr. Winickoff's experience in tobacco control and his experience make him well-qualified to offer his opinions in this case. For example, Dr. Winickoff has published more than 150 peer-reviewed publications on tobacco control issues, including on effect of exposure to tobacco product promotion in advertising, media, and film, the causes of initiation of tobacco use in youth, the role of flavors in tobacco products, epidemiology of e-cigarette product use in youth and young adults, and potential solutions to e-cigarette use among adolescents, and was selected by the American Academy of Pediatrics to

¹⁰¹ As Plaintiffs informed Defendants on December 3, 2021, Plaintiffs are not seeking to offer the opinions of Dr. Eissenberg or Dr. Shihadeh relating to Altria.

represent the Academy in testimony before Congress at hearings examining JUUL's role in the youth nicotine epidemic. *Id.* at 4-7. ¹⁰²

Dr. Winickoff offers much more than just *ipse dixit* to support his opinions: as indicated in his report and his deposition testimony, he based his conclusions on what he found after searching through "a large database of documents [and] pulling together experiences and [his] research experience over the past 20 years." JLI Ex. 54, Winickoff Dep. (11/5/21) at 25:6-15, 274:20-276:19 (describing his process of searching through a database of millions of documents, reviewing the medical literature, and reviewing depositions, including his review of documents relating to Altria); Shafer v. C.R. Bard, Inc., C20-1056RSM, 2021 WL 4305216, at *3 (W.D. Wash. Sept. 22, 2021) ("[T]he review of Defendants' internal documents and the reports of [another expert] appear to be a sound methodology for developing [the expert's] opinion"). JLI Ex. 25, Winickoff Rpt. at 165-166 (citing documents and deposition testimony). Id. at 227 (citing documents and testimony).

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¹⁰² Dr. Winickoff also served for 7 years as the Chair of the American Academy of Pediatrics (AAP) Julius Richmond Center of Excellence Tobacco Consortium, leading a national group of researchers to address tobacco control issues that affect youth. *Id.* at 2. He currently serves as Director of Translational Research for the AAP Richmond Center, where on behalf of over 50,000 AAP member pediatricians in the United States, he translates tobacco control research into clinical practice, public policy, and real-world community strategies using tobacco control initiatives to improve the public health of the nation's youth. *Id.* at 2. Dr. Winickoff is also the Director of Pediatric Research at the Massachusetts General Hospital (MGH) Tobacco Research and Treatment Center where he collaborates with the many researchers at MGH and in the broader Harvard system who study tobacco control. Dr. Winickoff has received numerous awards, including the HHS Secretary's Award for Distinguished Service for "protecting the health of the United States public," and the Academic Pediatric Association Health Policy Award for cumulative public policy and advocacy efforts that have improved the health and well-being of infants, children, and adolescents. *Id.* at 3.

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Dr. Winickoff then concluded, based on his extensive experience with tobacco control, the causes of initiation of tobacco use in youth, and the impact of e-cigarettes on youth, that in his opinion, it was "irresponsible and reckless for Altria, knowing what it knew about JUUL and about the youth nicotine epidemic, to provide help and support and encouragement to JLI to expand the sales of JUUL." JLI Ex. 25, Winickoff Rpt. at 227; *see also* JLI Ex. 25, Winickoff Rpt. at 222-229 (

That Altria disagrees with the evidence he relied on or the conclusions he reached goes to weight, not admissibility. *Hangarter v. Provident Life and Accident Ins. Co.*, 373 F.3d 998, 1017 n. 14 (9th Cir. 2004) (finding that questions regarding the nature of the evidence relied on by the expert go to the weight of the testimony, "an issue properly explored during direct and cross-examination" (citing *Children's Broad. Corp. v. Walt Disney Co.*, 357 F.3d 860, 865 (8th Cir. 2004) ("[T]he factual basis of an expert opinion goes to the credibility of the testimony, not the admissibility, and it is up to the opposing party to examine the factual basis for the opinion in cross-examination.") (citation and quotation marks omitted))); *see also Siring v. Oregon State Bd. of Higher Educ. ex rel. E. Oregon U.*, 927 F. Supp. 2d 1069, 1074 (D. Or. 2013) (When an expert reviewed "deposition transcripts of Defendant's witnesses, their email communications, [and] documents produced in discovery," critiques about conclusions or construing evidence in Plaintiffs' favor are for cross examination). 103

To the extent Altria is arguing that Dr. Winickoff's description of the facts underlying his opinions is a narrative, the proper time to that objection is at trial. *In re Yasmin and YAZ (Drospirenone) Mktg., Sales Practices and Products Liab. Litig.*, 3:09-MD-02100-DRH, 2011 WL 6302287, at *8 (S.D. Ill. Dec. 16, 2011) ("As to defendant's argument regarding narrative testimony, the Court has broad discretion over the mode and order of examining witnesses and presenting evidence and may allow testimony in narrative form at trial if the Court finds that it would helpful to the jury."); *In re Actos (Pioglitazone) Products Liab. Litig.*, 12-CV-00064, 2014 WL 120973, at *10 (W.D. La. Jan. 10, 2014) ("The objection that testimony is 'narrative' is an objection as to form, foundation, or responsiveness, and must be presented at trial"); *In re Testosterone Replacement Therapy Products Liab. Litig. Coordinated Pretrial Proceedings*, 14 C 1748, 2017 WL 1836443, at *15 (N.D. Ill. May 8, 2017) ("[T]o the extent [the expert] is summarizing voluminous records and materials, as appears to be the case, this aspect of his

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G. Conclusion

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For all the foregoing reasons, Altria's *Daubert* motion should be denied.

XII. **ODD MOTION**

The Court should deny the *Daubert* motion by Defendants Nicholas Pritzker, Riaz Valani, and Hoyoung Huh (collectively, Other Director Defendants or ODDs¹⁰⁴). ODD Mot., ECF 2686. ODDs primarily challenge the opinions of Dr. Drumwright, Boyles, and Johnson. None of their arguments provides any basis for excluding any portion of those experts' opinions. Each of the experts is well-qualified in the relevant field, has extensively reviewed the facts of this case, and offered opinions that are relevant to key issues involving ODDs' liability. Separately, ODDs offer scattershot challenges to a range of experts based on claims that the experts simply recite documents or refer to ODDs in prejudicial terms. In both instances, the experts are discussing the relevant facts and the conclusions they draw from those facts. To the extent any phrases used in the reports could be considered unduly prejudicial, the experts can use different wording at trial.

Drumwright's Opinions Concerning Corporate Conduct are Admissible Α.

ODDs seek to exclude the opinions of Dr. Drumwright on several grounds, none of which has merit. First, ODDs' arguments concerning her qualifications are based on ODDs' distortion of the opinions Dr. Drumwright is actually offering. Second, Dr. Drumwright's opinions are sufficiently reliable because she applies industry standards to the evidence in this case. Lastly, her opinions are relevant to the issue of whether the ODDs' conduct was consistent with the standard of care for corporate directors, an issue that goes directly to the question of the reasonableness of their conduct.

1. Dr. Drumwright is Qualified to Give Her Opinions.

Dr. Drumwright readily meets the expert qualification standard. "The qualification standard is meant to be broad and to seek a 'minimal foundation' justifying the expert's role as an expert."

testimony is properly admitted under Federal Rule of Evidence 1006 as well as Rule 702 in the sense that he is identifying what he, given his background and expertise, considers to be the most salient aspects of those voluminous materials.").

¹⁰⁴ Although Huh, Pritzker, and Valani refer to themselves as the "Non-Management Defendants," Plaintiffs use the "Other Director Defendant" terminology utilized by the Court.

Allen v. Am. Cap. Ltd., 287 F. Supp. 3d 763, 776 (D. Ariz. 2017) (citing Hangarter v. Provident Life & Acc. Ins. Co., 373 F.3d 998, 1015–16 (9th Cir. 2004). Dr. Drumwright offers two opinions concerning ODDs: that they violated the standard of care for corporate directors and that they acted in their own self-interest instead of the interests of their stakeholders when conflicts of interest arose. Dr. Drumwright is qualified to give those opinions because her experience and expertise are at the intersection of marketing, ethics, and corporate governance.

Dr. Drumwright has a Ph.D. in Business Administration from the University of North Carolina-Chapel Hill, is a highly decorated professor at the University of Texas-Austin, and has been an academic and administrator for over thirty years. JLI Ex. 5, Drumwright Rpt. at 1-6 and Ex. A at 1-5; JLI Ex. 34, Drumwright Dep. at 258:2-7. She has taught and conducted research at several highly ranked research institutions, including Harvard University. JLI Ex. 5, Drumwright Rpt. at 2 and Ex. A at 1-2. Her research focuses on ethics in advertising, strategic marketing communication, and understanding how and why boards behave unethically—a subject on which she has published multiple articles in peer-reviewed journals and book chapters. *Id.* at 2-3 and Ex. A at 5-8. She has presented her research nationally and internationally and won multiple awards. *Id.* at 2-3 and Ex. A at 3. She teaches both undergraduate and graduate courses that cover ethics and corporate responsibility. *Id.* at 3-4; JLI Ex. 34, Drumwright Dep. at 258:24-259:15. She has taught issues related to boards of directors specifically for many years in multiple courses. JLI Ex. 5, Drumwright Rpt. at 3-4; JLI Ex. 34, Drumwright Dep. at 258:15-19 ("I certainly have taught issues related to boards of directors for many years in multiple courses, so it's something that I ... consider as part of my wheelhouse.").

Because of her experience and extensive research, she is well versed in the scientific and academic literature surrounding corporate ethics, and in the standards and codes of conduct that govern how corporate directors should conduct themselves. JLI Ex. 5, Drumwright Rpt. at 1, 109-18 (discussing professional standards for corporate boards), 118-21 (discussing conflict of interests faced by corporate boards)). Dr. Drumwright also has decades of experience serving on both corporate and non-profit boards, including the American Marketing Association Foundation Board.

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Id. at 3; JLI Ex. 34, Drumwright Dep. at 251:23-252:14, 253:16-18. Dr. Drumwright is qualified to opine on both the standard of care and conflicts of interest of corporate directors.

Defendants try to manufacture a *Daubert* issue by characterizing Dr. Drumwright's opinions as "corporate governance opinions" and then declaring that she is not an expert in "corporate governance." The Court should reject these arguments. First, the Court does not need to define "corporate governance" or determine whether Dr. Drumwright's opinions lie within that definition. It needs only to determine whether she is qualified to give the opinions she offers. *See In re Bard IVC Filters Prod. Liab. Litig.*, No. MDL 15-02641-PHX DGC, 2018 WL 495187, at *2 (D. Ariz. Jan. 22, 2018) ("The Court does not find it helpful to cast the issue in terms of ethics vs. non-ethics, but instead will focus on Dr. Eisenberg's specific assertions and the bases for them.").

Second, even using ODDs' definition of corporate governance, Dr. Drumwright is an expert. ODDs argue that corporate governance "includes all aspects of corporate board behavior." ODD Mot. at 7 (citing *In re NVIDIA Corp. Derivative Litig.*, No. C-06-06110-SBA(JCS), 2008 WL 5382544, at *1 (N.D. Cal. Dec. 22, 2009)). Ethics and conflicts of interest fall within this broad definition because they are aspects of corporate board behavior. *See, e.g., Emond v. Murphy*, No. LACV1809040JAKJEMX, 2019 WL 13039332, at *2 (C.D. Cal. Aug. 27, 2019) (changes to business ethics practices were changes to corporate governance). Additionally, an expert does not need to be "the most specialized possible expert to opine on a subject." *Zeiger v. WellPet LLC*, 526 F. Supp. 3d 652, 672 (N.D. Cal. 2021). She need only have "expertise from [her] experience." *Id.*; *see also Houserman v. Comtech Telecomms. Corp.*, 509 F. Supp. 3d 1301, 1304 (W.D. Wash. 2020) (accountant was an expert on corporate governance as it concerns internal controls and accounting standards); *In re Novatel Wireless Sec. Litig.*, No. 08CV1689 AJB RBB, 2012 WL 5463214, at *4 (S.D. Cal. Nov. 8, 2012) (lawyer was an expert on corporate governance concerning a specific trading plan). Dr. Drumwright is an expert in corporate governance where it intersects with marketing and ethics.

The cases cited by ODDs are irrelevant here. In those cases the experts had no expertise related to their excluded opinions, but here Dr. Drumwright is offering opinions related to fields in which she has ample expertise. See Planned Parenthood Fed'n of Am., Inc. v. Ctr. for Med.

Progress, 402 F. Supp. 3d 615, 717, 720-21 (N.D. Cal. 2019) (professor of constitutional and gender law could testify on the background and history of anti-abortion activities but could not opine on causation, damages, intent, or foreseeability); *cf. Pooshs v. Phillip Morris USA, Inc.*, 287 F.R.D. 543, 547–48 (N.D. Cal. 2012) (naturopathic physician was not an expert in researching document archives); *Stonefire Grill, Inc. v. FGF Brands, Inc.*, 987 F. Supp. 2d 1023, 1039 (C.D. Cal. 2013) (expert not admitted because, *inter alia*, he had only given presentations tangential to the subject matter, had never written about or testified about the subject matter, and the data on which the expert relied was invalidated and irrelevant).

Dr. Drumwright has considerable education, knowledge, and expertise in the areas of marketing, ethics, and corporate governance. The standard of care owed by corporate directors and the conflicts of interest they face are, therefore, in her "wheelhouse." *See Zeiger*, 526 F. Supp. 3d at 672 (expert opinion that defendant could have tested pet food was within the "wheelhouse" of an expert in animal nutrition). Dr. Drumwright is qualified to give her expert opinions.

2. <u>Dr. Drumwright's Opinions Are Reliable.</u>

Dr. Drumwright's opinions on ethics and corporate governance are reliable because she has expertise in the field and applied relevant professional standards to the facts.

Expert testimony is reliable "if the knowledge underlying it has a reliable basis in the knowledge and experience of the relevant discipline." *Houserman*, 509 F. Supp. 3d at 1303 (citing *Primiano v. Cook*, 598 F.3d 558, 565 (9th Cir. 2010)). When the area of expertise is a social science and "the research, theories and opinions cannot have the exactness of hard science methodologies, trial judges are given broad discretion to determine whether Daubert's specific factors are, or are not, reasonable measures of reliability in a particular case." *Golden W. Trading*, 2012 WL 12953447, at *1 (quoting *United States v. Simmons*, 470 F.3d 1115, 1123 (5th Cir. 2006)); *In re Packaged Seafood Prod. Antitrust Litig.*, No. 15-MD-2670 JLS (MDD), 2020 WL 5739316, at *4 (S.D. Cal. Sept. 24, 2020) (finding that reliability of sociology professor's opinions "will depend heavily on the knowledge and experience of the expert, rather than the methodology or theory behind it") (internal citations omitted). Thus, courts may look to "other indicia of reliability . . . including professional experience, education, training, and observations." *Golden W. Trading*,

2012 WL 12953447, at *1; see also City of Myrtle Beach, 504 F.Supp.3d at 517 (stating that in the social sciences field "experience is the predominant, if not sole, basis for a great deal of reliable expert testimony"). Additionally, an expert's analysis of facts using industry standards demonstrates that the expert applied their specialized knowledge and experience. *Houserman*, 509 F. Supp. 3d at 1304 (allowing opinion of accountant who applied his expertise and used industry standards to explain accrual accounting and evaluate the party's conduct).

As discussed above, Dr. Drumwright has dedicated her career and research to corporate ethics and has written and taught the subject for over thirty years. She applied this knowledge and experience to the data when she outlined the different professional standards that apply to corporate boards, JLI Ex. 5, Drumwright Rpt. at 109-18, defined and explained conflicts of interest as they relate to corporate directors, *id.* at 118-21, and then analyzed ODDs' conduct with reference to those standards and principles. *Id.* at 121-54. Dr. Drumwright's opinions are reliable because she applied her expertise gained through experience to the facts, using professional standards of corporate boards. *See, e.g., Houserman*, 509 F. Supp. 3d at 1304.

Defendants attempt to undercut Dr. Drumwright's reliability by repeatedly asserting that she "selectively" reviewed the facts. But Dr. Drumwright's review of the facts in this case was extensive. *See* JLI Ex. 5, Drumwright Rpt., Ex. A; JLI Ex. 34, Drumwright Dep. at 16-25, 35:16-22. And, even if she was selective, that fact would not affect the admissibility of her opinions. *See Packaged Seafood*, 2020 WL 5739316, at *4 (citing *Kennedy v. Collagen Corp.*, 161 F.3d 1226, 1231 (9th Cir. 1998)) (finding defendant's "cherry-picking" argument unpersuasive because "[t]here is no rule that an expert must consider and discuss all of the evidence on the record in order to proffer admissible testimony," and matters not relied upon are grounds for cross-examination). Dr. Drumwright's opinions are reliable.

3. <u>Dr. Drumwright's opinions are relevant.</u>

Dr. Drumwright's opinions are relevant because the jury must apply a standard of care to ODDs, and Dr. Drumwright helps to define that standard of care and will help the jury decide whether ODDs' conduct failed to meet that standard. An expert opinion is relevant "if the knowledge underlying it has a valid connection to the pertinent inquiry." *Houserman*, 509 F. Supp.

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3d at 1303; see also In re Homestore.com, Inc., No. CV 01-11115 RSWL CWX, 2011 WL 291176, at *10 (C.D. Cal. Jan. 25, 2011) (expert opinions are helpful to the jury when they assist it in understanding or determining a fact in issue in the case). When a jury must apply a standard of care to a defendant, courts "routinely" admit testimony that "inform[s] the jury about the standard of care and the scope of [defendant's] duties." AngioScore, Inc. v. TriReme Med., Inc., 87 F. Supp. 3d 986, 1016 (N.D. Cal. 2015), rev'd and remanded on other grounds sub nom. AngioScore, Inc. v. TriReme Med., LLC, 666 F. App'x 884 (Fed. Cir. 2016) (collecting cases); Wattel v. Browne, No. 02-CV-2256-PHX-PGR, 2006 WL 1211186, at *1 (D. Ariz. May 3, 2006) ("[T]he Court will instruct the jury regarding the legal duties the Defendants owed However, the standards of care that make up those duties and what conduct constitutes a breach of those duties are factual questions and proper subjects for expert testimony."). Similarly, courts will permit experts to opine on the "practices generally applied in the corporate context to control for potential conflicts of interests" and how a defendant's actions differed from those practices. AngioScore, Inc., 87 F. Supp. 3d at 1016 (denying motion to exclude expert).

Here, Dr. Drumwright opines on the standard of care ODDs owed. She explains many different industry standards of care and corporate conflicts of interest. Dr. Drumwright then analyzes what ODDs said and did within those contexts. These opinions will assist the jury in determining whether ODDs' actions were reasonable under the circumstances, including what ODDs knew and did not know at the time they acted.

ODDs categorically assert that "[e]thical sources cannot assist the jury in determining potential legal liability," and then cite cases in which a non-ethics expert opined on ethics. *See*, *e.g.*, *In re Bard IVC Filters Prods. Liab. Litig.*, No. MDL 15-02641-PHX DGC 2017 WL 6523833, at *9 (D. Ariz. Dec. 21, 2017) (medical doctors with no ethical expertise gave "ethical" opinions based solely on their personal views of corporate ethics and morality); *In re Bard*, 2018 WL 495187, at *3 (medical doctor did not have the "scientific, technical, or otherwise specialized knowledge" to opine on proper corporate behavior); *In re Baycol Prods. Litig.*, 532 F. Supp. 2d 1029, 1053 (D. Minn. 2007) (medical doctor could not "infuse his personal views as to whether Bayer acted ethically, irresponsibly or recklessly" when he had no expertise in ethics); *In re Diet Drugs*

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(Phentermine, Fenfluramine, Dexfenfluramine) Prod. Liab. Litig., No. MDL 1203, 2000 WL 876900, at *9 (E.D. Pa. June 20, 2000) (experts not qualified to opine on corporate ethics when their disciplines did not include knowledge or experience on corporate behavior and the associated standards, pressures, and influences). These cases are inapposite to Dr. Drumwright because they were all decided based on lack of expertise, and Dr. Drumwright has the expertise to opine about corporate ethics.

ODDs also cite *In re Rezulin Prod. Liab. Litig.*, 309 F. Supp. 2d 531, 545 (S.D.N.Y. 2004), to argue that Dr. Drumwright's opinions are too vague to help the jury, and that her opinions will confuse the jury and "prejudice" Defendants. ODD Mot. at 9, 11-12. In *Rezulin*, like the cases discussed above, the experts seeking to opine on ethical obligations did not have expertise in ethics at all, let alone the ethical responsibilities of the defendant (a pharmaceutical company). *Rezulin*, 309 F. Supp. at 542-43. Since they had no expertise, the bases for their opinions were personal, subjective views, and the ethical standards they offered were vague and unhelpful. *Id.* The *Rezulin* court thus excluded these opinions as unfairly prejudicial. *Id.* at 545. Dr. Drumwright, by contrast, has extensive expertise in ethics generally and in the ethical obligations of corporate directors specifically. She applied this expertise and ethical standards to the facts and explained her analysis and conclusions in detail. Her opinions will not confuse the jury or unfairly prejudice ODDs and should be admitted.

Finally, Dr. Drumwright's opinions will not take the place of the judge or jury. *See United States v. Holmes*, No. 5:18-CR-00258-EJD-1, 2021 WL 2035177, at *4–5 (N.D. Cal. May 21, 2021) (rejecting arguments that opinions about industry standards constituted improper legal conclusions and would not be helpful to the jury). An expert is "permitted wide latitude to offer opinions, including those that are not based on firsthand knowledge or observation." *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 592 (1993); *Houserman*, 509 F. Supp. 3d at 1305 (opinions based on analysis of the facts will "certainly require a review or 'summarizing' of the evidence and application of [] specialized knowledge and background[,]" and do not invade the province of the jury).

Dr. Drumwright's opinions are within this wide latitude. Her opinions inform the jury about the standard of care, but do not assert a legal standard. JLI Ex. 34, Drumwright Dep. at 146:1-147:6. Her opinions review and summarize the evidence, applying her specialized knowledge to the facts, but they do not attempt to make legal judgments. *See generally* JLI Ex. 5, Drumwright Rpt.; *see also* JLI Ex. 34, Drumwright Dep. at 51:14-22, 331:332:7. Her opinions analyze and compare ODDs' words and actions against the standards of conduct that apply to them, but she does not offer credibility determinations. JLI Ex. 34, Drumwright Dep. at 288:3-15.

To the extent ODDs argue that the way Dr. Drumwright presents her opinions is improper, that is a question of how she will testify, not the admissibility of her opinions. *See*, *e.g.*, *Homestore.com*, *Inc.*, 2011 WL 291176, at *10 (admitting experts' opinions but cautioning not to testify to legal conclusions at trial); *AngioScore*, 87 F. Supp. 3d at 1016 (admitting corporate governance expert's opinions on governance practices and conflicts of interest with warning not to testify on the ultimate issue of fact). Dr. Drumwright will, of course, abide by the rules and procedures of this Court in giving her opinions. Dr. Drumwright's opinions should be admitted.

B. <u>Boyles's Opinions Are Relevant to Determining Restitution for ODDs</u>

ODDs seek to exclude the entirety of the Boyles report, but almost none of their arguments concern his methodology for determining how lower per-unit market prices (as estimated by Dr. Singer) would have impacted Altria's investment and corresponding payments to ODDs. Instead, ODDs' arguments misconstrue the law and make arguments that (at most) go to the weight of Boyles's conclusions, not the reliability of his methodology.

ODDs make two preliminary arguments, both of which the Court should reject. First, ODDs suggest that Boyles seeks to have the class assert claims on behalf of Altria and to "estimate[] an amount by which Altria allegedly overpaid." ODD. Mot. at 13. 105 To the contrary, Boyles's analysis focuses squarely on the restitution and disgorgement claims asserted by the class,

¹⁰⁵ Boyles offers no opinions about whether Altria "overpaid" for its investment in JLI based on the information available and revenues at the time of the investment. Instead of claiming that Altria "overpaid," Boyles estimates the outcome of Altria's valuation models under a different set of circumstances, *i.e.* lower revenues.

Id. ODDs cite no authority for the proposition that a damages expert cannot base his or her calculations on an assumption of wrongdoing—no matter how significant. Calculating and estimating damages based on a jury finding of liability is the core function of a damage expert.

The Court should also reject ODDs' fit and reliability challenges.

1. <u>Boyles's Opinions are Relevant to the Classes' Restitution and Disgorgement Claims.</u>

ODDs' primary fit argument is that Boyles's opinion has no bearing on recovery here, because a restitution claim requires that a defendant have obtained the specific funds that the plaintiff or class member lost. ODD Mot. at 14. But the Court has considered and rejected that argument multiple times. *See* MTD Order I, 497 F. Supp. 3d at 640 (noting the "well-established case law" holding that restitution can result from indirect payments); MTD Order II, 533 F. Supp. 3d at 876 (holding, in rejecting arguments by ODDs, that restitution requires only financial gain by the defendant and financial loss by the plaintiff).

ODDs also misapprehend the purpose of Boyles's opinions. A restitution calculation has two components: what the class lost and what the defendant gained. MTD Order II, 533 F. Supp. 3d at 876 (applying prior holding that "Plaintiffs simply need to allege that JLI obtained money (or property) and that plaintiffs lost money or property as a result of defendants' unfair practices" to ODDs). In this case, Dr. Singer calculates what the class lost, and Boyles calculates what the defendants (ODDs) gained. Plaintiffs *are not* asserting that the gain received by the ODDs, as calculated by Boyles, is the sole component of a restitution calculation under the UCL or FAL. Fischel's statement that Boyles's opinions are "irrelevant to any issue of measuring harm or determining damages" (ODD Ex. F, Fischel Rpt. at ¶ 12) is incorrect as a matter of law. And the

¹⁰⁶ The amount of restitution cannot be greater than either amount. Thus, if Boyles determines that the value ODDs received as a result of the wrongful conduct is greater than the damages paid by the class as calculated by Dr. Singer, then the amount of restitution would be equal to the damages amount.

cases ODDs cite are inapposite, as in both of those cases, the plaintiffs sought to calculate restitution without any consideration of what the plaintiff lost (what those courts referred to as "non-restitutionary disgorgement"). *Krommenhock v. Post Foods, LLC*, 334 F.R.D. 552, 577-78 (N.D. Cal. 2020) (the only restitution model on which plaintiffs relied was a full refund that failed to account for actual consumer loss); *Hadley v. Kellogg Sales Co.*, 324 F. Supp. 3d 1084, 1112-14 (N.D. Cal. 2018) (same). Here, Plaintiffs—through Dr. Singer and Boyles—are accounting for both necessary components of a restitution calculation.

In addition, ODDs are incorrect that traditional disgorgement (which is non-restitutionary because it focuses only on the defendant's gain and not the plaintiffs' loss) is unavailable under Plaintiffs' unjust enrichment claim. ODDs rely on a single case from 2017 for that assertion, but Plaintiffs have repeatedly briefed this issue and noted that the Ninth Circuit in 2020 clarified that "California law recognizes a right to disgorgement of profits resulting from unjust enrichment, even where an individual has not suffered a corresponding loss," and "regardless of whether a defendant's actions caused a plaintiff to directly expend his or her own financial resources or whether a defendant's actions directly caused the plaintiff's property to become less valuable." *In re Facebook, Inc. Internet Tracking Litig.*, 956 F.3d 589, 599–600 (9th Cir. 2020)); *see also Cottrell v. AT&T*, 2020 WL 4818606, at *4 ("a plaintiff need not show damages to recover for unjust enrichment"). (N.D. Cal. Aug. 19, 2020) For this reason, Boyles's calculation of what ODDs gained as a result of the unlawful conduct is itself a proper measure of relief for Plaintiffs' unjust enrichment claim.

Lastly, in a footnote, ODDs argue that Boyles's report validates the concerns expressed by the Court previously regarding the potential challenges of calculating restitution for the ODDs. ODD Mot. at 14-15 n.3. The Court previously questioned whether the evidence would show "how the [Founder] and Director Defendants were compensated and as a result of what guarantees, metrics or other compensation structures were in place." MTD Order I, 497 F. Supp. 3d at 640. Boyles's opinions and analysis directly address those issues. Each of ODDs' footnote critiques (none of which cites to any evidence in the record) is incorrect and irrelevant, and in any event, go to the weight of Boyles's opinions, not their admissibility.

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ODD Mot. at 14-15 n.3. The argument is flawed and ineffective, however, because ODDs ignore the fact that Boyles never offers the opinion that valuation decreases could or should be combined in that manner. In any event, ODDs' argument at most reflects a dispute among experts and not a *Daubert* issue. Boyles also does not express any opinion that all JLI stockholders should be liable, or even that ODDs committed legal violations; he was simply asked to assess the impact of the alleged wrongful conduct on the payments ODDs received as a result of the Altria investment.

2. <u>Boyles's Analysis Is Methodologically Sound.</u>

ODDs contend that Boyles's opinions should be excluded because Dr. Singer's opinions should be excluded. But Dr. Singer has not submitted a merits report yet, and ODDs instead cite to defendants' *Daubert* motions for class certification (which the Court has tentatively said it would deny). ODDs are also incorrect that Mr. Boyles "relies" on Dr. Singer. Boyles's methodology—is sound and reliable regardless of whether the jury agrees with the input provided by Dr. Singer.

See ODD Ex. D, Boyles Rpt. at ¶ 56

ODDs also argue that Boyles's opinions suffer from methodological defects, but they do not discuss or critique his methodology. Instead, they argue that Boyles's (and Dr. Singer's) *conclusions* should be rejected because they are purportedly inconsistent with the marketplace today. ODD Mot. at 16-17. But Boyles's opinions provide a reliable methodology for how the valuation in 2018 would have changed absent the wrongful conduct, and on this point ODDs offer no meaningful criticism.

For example, ODDs argue that Boyles misapplies Dr. Singer's analysis. Dr. Singer calculates the market price that would have prevailed absent Defendants' wrongful conduct. A lower market price, in turn, results in lower per-unit revenues

ODD Ex. D, Boyles Rpt. at ¶ 50. While

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ODDs appear to dispute whether knowledge of addiction and safety risks would decrease per-unit revenues (ODD Mot. at 16), that argument is best addressed to Dr. Singer; it has nothing to do with Boyles's methodology. In addition, lower per-unit revenues at the time of the valuation would have impacted any assumptions about future profitability and revenue generation. *See* ODD Ex. D, Boyles Rpt. at ¶ 58 (

Description of JUULpods *today* therefore has little bearing on projected valuations in 2018. More importantly, because Boyles uses the parties' actual valuation in 2018 as his starting point, any forward-looking considerations the parties may have had in 2018 were accounted for in Boyles's analysis. In any event, ODDs' arguments in this regard go to the weight, not the admissibility of Boyles's opinions. This is particularly true given the fact that any uncertainty in damages in a "but-for" world should be construed against the party whose illegal conduct created that uncertainty. *See Bigelow v. RKO Radio Pictures, Inc.*, 327 U.S. 251, 265 (1946) ("The most elementary conceptions of justice and public policy require that the wrongdoer shall bear the risk of the uncertainty which his own wrong has created.").

None of ODDs' other critiques (ODD Mot. at 16-17) has merit.

ODD Ex. D, Boyles Rpt. at ¶ 34. To the extent the factfinder concludes that the reduction in revenues (as calculated by Dr. Singer) should only apply to the U.S. portion of the valuation models, Boyles's methodology can readily account for that circumstance. Second, the fact that at some point after 2018 JLI discontinued selling certain flavors is irrelevant to the valuation in 2018. To the extent ODDs critique the application of a single per-unit market price reduction to different flavors, that argument would apply to Dr. Singer (who estimates the price reductions) and not Boyles (who only uses those price reductions as an input). Third, JLI's value today has nothing to do with how the 2018 valuation would have changed had per-unit prices (and

1	resulting revenues) been lower at that time. 107 Fourth, as noted above, Boyles does not assume that
2	JLI would have had negative value with a reduction in revenues.
3	Lastly, Plaintiffs' allegations concerning Altria's knowledge of youth usage at the time of
4	its investment do not undermine Boyles's opinions. Plaintiffs allege that Altria invested in JLI to
5	profit from JUUL's existing underage user base and future youth sales, and Altria's valuation of
6	JLI was higher <i>because</i> of its hold on young users. <i>See</i> SACCAC ¶ 510.
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8	See, e.g., Pltf. Ex. 27, Gifford
9	Dep. at 123. In the "but-for" world Boyles focuses on, such minor appeal and minor sales never
10	would have existed, resulting in lower revenues and lower valuation (and thus lower payments to
11	the ODDs). There is no inconsistency between Boyles's analyses and Plaintiffs' claims. ODDs'
12	arguments to contrary (ODD Mot. at 18) miss the mark because they assume that knowledge of
13	youth targeting in JUUL marketing would have lowered the valuation,
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16	And what a company like Altria would have done in but-for
17	world without the challenged conduct is a jury question, not a <i>Daubert</i> issue.
18	C. <u>Johnson's Opinions Are Both Relevant and Reliable.</u>
19	Robert Johnson's Rule 26 punitive damages report of September 17, 2021, as supplemented
20	by addendums dated November 5 and 10, 2021, succinctly discuss the financial condition of JLI,
21	Altria, Adam Bowen, James Monsees, and the ODDs. Only the ODDs have filed a Daubert motion
22	as to Mr. Johnson.
23	ODDs first argue that Johnson does nothing more than "regurgitate the [ODDs'] deposition
24	testimony." ODD Mot. at 19. Not so.
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27	107 Even if it made sense to consider JLI's current valuation, the fact that it is now much lower than
	ii — Even ii ii made sense to consider ti li s current valhanon, me taci mai ti is now milch lower man

See See
ODD Ex. H, Johnson Rpt.
Second, ODDs argue that Johnson uses the incorrect legal standards. ODD Mot. at 20-22.
Ultimately, "[w]hat is required [to support an award of punitive damages] is evidence of the
defendant's ability to pay the damage award." Baxter v. Peterson, 150 Cal. App. 4th 673, 680
(2007) (citation omitted). Here, ODDs' receipt of at least \$ in special dividends is directly
relevant to their ability to pay a punitive damage award should the jury find punitive damages
appropriate. When and if that occurs, ODDs will be free to present their own evidence of their
ability to pay, including any alleged philanthropic gifts or other dissipation of the special dividends
they received.
The 2012 California Court of Appeal decision in Bankhead v. ArvinMeritor, 205 Cal. App.
4th 68 (2012), is particularly instructive concerning the relevance of Johnson's opinions. In
Bankhead, the Court of Appeals upheld Johnson's trial testimony as to the financial condition, for
punitive damage purposes, of asbestos defendant ArvinMeritor, Inc. The court endorsed Johnson's
focus on profits ArvinMeritor earned from its tortious activity in selling asbestos-covered brake
pads with no cancer warnings, rejecting the Defendant's contention that Johnson's testimony was
defective for lack of discussions of Defendant's "net worth":
[b]oth California and the federal authorities agree that profits earned
from tortious activity that supports an award of punitive damages are appropriately considered in the amount awarded." "the
[California] Supreme Court has expressly declined to adopt net worth as the standard for determining a defendant's ability to pay in any

given situation...." It agreed that "[n]et worth is too easily subject to manipulation to be the sole standard for measuring a defendant's ability to pay."

Bankhead, 205 Cal. App. at 78-80.

ODDs' citation to *In re Davol, Inc./C.R. Bard, Inc. Polypropylene Hernia Mesh Prods. Liab. Litig.*, 2021 WL 2646771, at *3-4 (S.D. Ohio June 28, 2021), is misplaced. In *Davol*, exclusion of Johnson's testimony hinged upon his focus on the financial condition of a non-party parent company that agreed to indemnify the subsidiary defendant, but which had not participated in the conduct at issue in the lawsuit, and which had not been sued—a situation not present here, where the conduct of the ODDs is directly at issue. Similarly, in *Pooshs v. Philip Morris USA, Inc. et al.*, 287 F.R.D. 543, 549-550 (N.D. Cal. 2012), Johnson was allowed to testify as to the current net worth of Philip Morris USA, Inc. and R.J. Reynolds but not their historical financial situations, because the plaintiffs in that case had made no showing that anything other than current net worth was relevant. Here, in contrast, plaintiffs allege that ODDs reaped extraordinary profits from the very tortious conduct at issue in the litigation, profits highly relevant to their financial condition for purposes of an award of punitive damages.

Lastly, ODDs argue that Johnson "measures damages" not attributable to ODDs. ODD Mot. at 20. Johnson does not measure "damages," he analyzes "the financial condition of the following individuals, specifically in relation to the economic benefit received as Special Dividends from JUUL Labs, Inc." ODD Ex. H., Johnson Rpt. at 4. In doing so, he appropriately focuses on the special dividends each earned from JLI;

following Altria's purchase

of 35% of JLI. In any event, ODDs's arguments that they did not personally receive the money go to the weight of Johnson's conclusions, not the reliability of the methodology.

Pritzker's argument that he was not the personal beneficiary of the special dividend is merely a distraction, as he admitted in his deposition that his investment in JLI and the special dividends received all belonged to his "family office," that he controls: "It's a family office. I would call it a family office. I think that's the closest thing, which has different aspects to it. There are no

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other investors, investor partners. We -- we do not manage money for other people, in other words." Pltf. Ex. 28, Pritzker Dep. 29:23-30:2; see also ODD Ex. L, Pritzker Dep. 195:11-15 (acknowledging receipt of "\$ with the proceeds from Altria's acquisition of 35 percent of Juul Labs, right? A. Correct.") Pritzker's effort to recharacterize the \$ profit is much like the "net worth" argument rejected by the Bankhead court as artificial and irrelevant for the financial condition check on punitive damage amounts:

Here, the jury was entitled to credit Johnson's uncontroverted testimony that ArvinMeritor was far wealthier than its stated net worth would indicate, and that net worth alone is an untrustworthy standard, because it is so easily manipulated.

Bankhead, 205 Cal. App. 4th at 82-83.

ODDs explain how this fact could impact the admissibility of Johnson's opinion, as opposed to his conclusions (which can be challenged at trial).

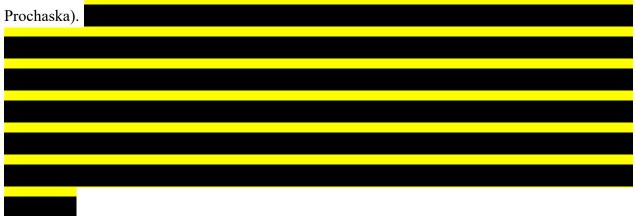
D. ODDs Provide an Insufficient Basis to Exclude Undefined Opinions from All Other Experts

Finally, ODDs offer a grab-bag of challenges to twelve experts who opine on the personal role of Riaz Valani, Nicholas Pritzker, and Hoyoung Huh in the alleged misconduct, and ask the Court to preclude those experts from discussing the ODDs at all. *See* ODD Mot. at 22 ("Eissenberg, Grunberg, Halpern-Felsher, Jackler, Levy, Lindblom, Pratkanis, Prochaska, Proctor, Ribisl, Shihadeh, and Winickoff should be precluded from testifying about the" ODDs). The motion

should be denied because each of these critiques goes to the weight of the expert opinions, not admissibility, and the critiques are not specified with sufficient detail in any event.

First, ODDs argue that the twelve challenged experts are not qualified "to offer expert opinions on matters of corporate control and the propriety of board actions," because, they assert, expertise in corporate governance is required to discuss any of their actions. ODD Mot. at 23. But these experts are not offering corporate governance opinions. Plaintiffs' experts explain that ODDs were leaders in JLI and key drivers of many company actions central to this case. The import of these opinions is not to evaluate ODDs' actions against the standards of corporate governance, but to explain how, as people within the company who participated in decision-making, they contributed to the alleged wrongdoing.

Second, ODDs repeat JLI's "Human Highlighter" arguments for expert opinions relating to their conduct. As discussed above, these arguments fail. Plaintiffs' experts' discussion about what ODDS "knew" or were "aware" of are properly supported and not the kind of ultimate determinations reserved for the jury. For example, ODDs challenge Prochaska's opinion that they "kn[ew] that their user base skewed underage and nicotine-naïve." ODD Mot. at 25 n.9 (quoting Prochaska).



At its core, ODDs' challenge is to the credibility of these experts' sources (namely, the testimony of Scott Dunlap) and their "methodology" in selecting documents and testimony to review and rely on. *See* ODD Mot. at 25-27. Such criticism of "the factual basis of an expert opinion goes to the credibility of the testimony, not the admissibility." *Hangarter v. Provident Life & Acc. Ins. Co.*, 373 F.3d 998, 1017 n.14 (9th Cir. 2004) (quoting *Children's Broad. Corp. v. Walt Disney Co.*, 357 F.3d 860, 865 (8th Cir. 2004)). In *Hangarter*, the Ninth Circuit rejected the argument that

ODDS made here, that an expert's "selection of documents to review went to the reliability of his 'methodology' as an expert"; it held that "the district court correctly surmised that questions regarding the nature of [the expert's] evidence went more to the 'weight' of his testimony—an issue properly explored during direct and cross-examination." *Id.* The same is true here.

Third, ODDs challenge various statements in expert reports under Rule 403. But Plaintiffs' experts are not "name calling and moralizing" as the ODDs suggest, ODD Mot. at 28; rather, they summarize large volumes of evidence supporting claims ranging from negligence to fraud and conspiracy. For example, evidence of the ODDs' knowledge of the cigarette industry and the Master Settlement Agreement supports conclusions that they knew or should have known that JUUL's marketing and design would attract youth, and that using methods known to attract youth would entice a big tobacco company like Altria to pay enormous sums of money to share in the profits and hedge against future risk to the cigarette industry.

ODDs also challenge particular language in Dr. Proctor's report that they characterize as "slanderous," *see* ODD Mot. at 29, echoing arguments also made by JLI, *see* JLI Mot. 1 at 29. As Plaintiffs explain more fully in response to JLI's first *Daubert* motion, Dr. Proctor is a well-qualified expert. In any event, Plaintiffs agree that Dr. Proctor will not use the handful of specific phrases cited by ODDs. ¹⁰⁸ To the extent ODDs seek to challenge any additional language from Dr. Proctor's report, their motion is insufficiently specific to allow an informed response.

Finally, Dr. Proctor's minimal references to ODDs' wealth are relevant, factual, and not prejudicial. The significant financial gain each of the ODDs received from the Altria deal is relevant to their motivations and mindsets generally as leaders of JLI. While ODDs have been dismissed from the B.B. bellwether trial, they remain defendants for claims including fraud and conspiracy in other cases, including the class case where their financial gain is relevant to Plaintiffs' restitution and disgorgement recoveries.

ODD Mot. at 30, the accuracy of Dr. Proctor's report is not in dispute:

¹⁰⁸ That Pritzker, Valani and Huh are "miscreants," analogies to the television show "Breaking Bad," and descriptions of Mr. Pritzker as "no stranger to conspiracy" and "nefarious." ODD Mot. at 29-30.

. V	alani testified that he received appro	eximately \$ as a result of the Altria deal that is at
th	ne heart of this case. ODD Ex. M, Va	lani Dep. at 37:14-23.
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ы Л	LI Ex. 20, Proctor Rpt. at 56, Plaintif	fs agree not to offer this fact into evidence in Phase I of the
B_0	ain trial.	
5	E. <u>Conclusion</u>	
7	For all the foregoing reasons, t	he ODDs' Motion should be denied.
\mathbf{x}	III. <u>CONCLUSION</u>	
)	For all the foregoing reasons,	Plaintiffs respectfully request that the Court deny each of
) D	befendants' Daubert motions.	
1 I	Dated: February 3s, 2022	Respectfully submitted,
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CERTIFICATE OF SERVICE

I hereby certify that on February 3, 2022, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system, which will automatically send notification of the filing to all counsel of record. I also caused a copy of the under-seal documents to be served via electronic mail on defense counsel.

By: /s/ Sarah R. London
Sarah R. London

Appendix A

1

Expert	Location of Discussion, Infra.
Boyles	Section XV.B.
Casey	Sections IX.B.5., X.A.2., X.C., XI.B.2.o., XII.B.2.b., XII.C.
Chandler	Sections V.C.2., V.D.4., XI.A.3., XI.B.2.e.
Cutler	Sections V.D.34., XI.B.2.k., XIII.C.
Drumwright	Sections V.C.2.c., V.D.4., V.F., XI.A., XI.B.2.a., XI.C.3., XIV.A., XV.A.
Eissenberg	Sections V.C.2.d., VI., XI.B.2.l., XII.B.2.b., XII.C., XII.D., XV.D.
Emery	Sections V.D.3.c., V.D.3.f., V.D.4., V.F.1., V.F.3. XI.C.3.
Grunberg	Sections V.B., V.C.2.b., V.C.2.d., V.D.3.f., V.E., VI., IX.B.8., XI.A.5., XI.A.5., XI.B.2.h., XIV.B., XV.D.
Halpern-Felsher	Sections V.C.2.b., V.D.3.b., V.D.3.f., V.F., IX.B.5., XI.B.2.b., XI.C.4., XV.D.
Jackler	Sections V.B., V.C.2., V.D.3.b., V.D.4., V.F., XI.A.2., XI.B.2.c., XIV.C., XV.D.
Johnson	Section XV.C.
Kelder	Section XIII.B.
Levy	Sections V.C.2., V.D.3.c., V.E., IX.B.7., IX.B.8., X.B., XI.A.6., XI.B.2.g., XII.B.2.b., XII.D.1., XV.D.
Lindblom	Sections XI.A.8., XI.B.2.j., XI.C.6., XV.D.
Noar	Sections V.C.2.d.,V.D.3.c., XII.B.
Pratkanis	Sections V.B., V.D.3.e., V.D.4., XI.B.2.d., XIV.D., XV.D.
Prochaska	Sections V.C.2., V.E., VI., IX.B.8., X.B.1, XI.B.2.i., XII.C.1., XII.D., XIV.E XV.D.
Proctor	Sections V.C.3., V.D.3.a., V.D.3.f., XI.A.1, XI.B.2.q., XV.D.
Pue	Section IX.
Ribisl	Sections V.F., XI.A.7, XI.B.2.p., XV.D.
Shihadeh	Sections V.C.2., VI. XI.B.2.m., XII.C.1, XII.D., XV.D.
Tackett	Sections IX., XII.B.2.b., XII.C.
Winickoff	Sections V.C.2., V.D.3.c., V.E., IX.B.6.a.iv., IX.B.7., IX.B.8., X.B., X.C., XI.B.2.n., XI.C.5., XIII.A., XIV.F., XV.D.
Woolley	Sections V.C.2.b., V.D.4., XI.A.4., XI.B.2.f.

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